Sunshine Act Meetings

Federal Register
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Friday, March 1, 1991

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL ENERGY REGULATORY COMMISSION

Notice of Closed Meeting

February 26, 1991.

The following notice of meeting is published pursuant to Section 3(a) of the Government in the Sunshine Act (Pub. L. No. 94–4109), 5 U.S.C. 552b:

DATE AND TIME: February 27, 1991, 9:00 a.m.

PLACE: 825 North Capitol Street NE, Room 9306, Washington, DC 20426.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

(1) Docket No. RP88–68–000, *et al.*, Transcontinental Gas Pipe Line Corporation.
(2) Docket No. IN89–1–000, Transcontinental Gas Pipe Line Corporation.
(3) Docket No. IN89–1–001, Transcontinental Gas Pipe Line Corporation.
(4) Transcontinental Gas Pipe Line Corporation, Sulpetro Limited Natural Gas.
(5) Docket No. TA85–3–29–009, *et al.*, Transcontinental Gas Pipe Line Corporation.

CONTACT PERSON FOR MORE INFORMATION: Lois D. Cashell, Secretary, Telephone (202) 208–0400.

The following Commissioners voted that agency business requires the holding of a closed meeting on less than the seven days' notice required under the Government in the Sunshine Act:

Chairman Allday
Commissioner Trabandt
Commissioner Moler
Commissioner Langdon
Commissioner Terzic

Lois D. Cashell,

Secretary.

[FR Doc. 91–5081 Filed 2–27–91; 4:00 pm]

BILLING CODE 6717–01–M

FEDERAL ELECTION COMMISSION

"FEDERAL REGISTER" NUMBER: 91–4283.

PREVIOUSLY ANNOUNCED DATE AND TIME: Thursday, February 28, 1991, 2:00 p.m., Meeting Open to the Public.

The above meeting will convene at 10:00 a.m., and not 2:00 p.m. as previously stated.

The following item had been added to the agenda:

Future Meetings

DATE AND TIME: Tuesday, March 5, 1991, 2:00 p.m.

PLACE: 999 E Street NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. § 437g.
Audits conducted pursuant to 2 U.S.C. § 437g, § 438(b), and title 26, U.S.C.
Matters concerning participation in civil actions or proceedings or arbitration.
Internal personnel rules and procedures or matters affecting a particular employee.

PERSON TO CONTACT FOR INFORMATION: Mr. Fred Eiland, Press Officer, Telephone: (202) 376–3155.

Hilda Arnold,

Administrative Assistant, Office of the Secretariat.

[FR Doc. 91–5046 Filed 2–27–91; 3:04 am]

BILLING CODE 6715–01–M

FEDERAL RESERVE SYSTEM: BOARD OF GOVERNORS

TIME AND DATE: 10:00 a.m., Wednesday, March 6, 1991.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets NW., Washington, DC 20551.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Summary Agenda

Because of its routine nature, no substantive discussion of the following item is anticipated. This matter will be voted on without discussion unless a member of the Board requests that the item be moved to the discussion agenda.

1. Proposed revision of Regulation P (Minimum Security Devices and Procedures for Federal Reserve Banks and State Member Banks) following zero-based review. (Proposed earlier for public comment; Docket No. R–0688.)

Discussion Agenda

2. Publication for comment of proposed amendments to Regulation CC (Availability of Funds and Collection of Checks) regarding certain Federal Reserve Bank services to be offered in a same-day settlement environment.

3. Any items carried forward from a previously announced meeting.

Note: This meeting will be recorded for the benefit of those unable to attend. Cassettes will be available for listening in the Board's Freedom of Information Office, and copies may be ordered for $5 per cassette by calling (202) 452–3684 or by writing to: Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, DC 20551

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board, (202) 452–3204

Dated: February 27, 1991.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 91–4983 Filed 2–27–91; 10:44 am]

BILLING CODE 6210–01–M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

TIME AND DATE: Approximately 10:30 a.m., Wednesday, March 6, 1991, following a recess at the conclusion of the open meeting.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: February 27, 1991.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 91–4984 Filed 2–27–91; 10:44 am]

BILLING CODE 6210–01–M

RESOLUTION TRUST CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 2:06 p.m. on Tuesday, February 26, 1991, the Board of Directors of the Resolution Trust Corporation met in closed session to consider matters relating to the resolution of failed thrift institutions.

In calling the meeting, the Board determined, on motion of Director C.C.

Hope, Jr. (Appointive), seconded by Director Robert L. Clarke (Comptroller of the Currency), concurred in by Chairman L. William Seidman, Vice Chairman Andrew C. Hove, Jr. and Director T. Timothy Ryan, Jr. (Director of the Office of Thrift Supervision), that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(4), (c)((8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10) of the "Government in the Sunshine Act" (5 U.S.C. 552b (c)(4), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10)).

The meeting was held in the Board Room of the Federal Deposit Insurance Corporation Building located at 550—17th Street NW., Washington, DC.

Dated: February 26, 1991.

Resolution Trust Corporation.

John M. Buckley, Jr.,

Executive Secretary.

[FR Doc. 91-4995 Filed 2-27-91; 10:51 am]

BILLING CODE 6714-01-M

federal register

Friday
March 1, 1991

Part II

Department of Health and Human Services

Health Care Financing Administration

42 CFR Parts 400, et al.

Medicare and Medicaid Programs; OBRA '87 Conforming Amendments; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 400, 405, 406, 408, 409, 410, 413, 416, 417, 424, 430, 431, 435, 436, 440, 441, 447, 455, 482, 485, 489, 491, and 498

[BPD-484-FC; RIN 0938-AD92]

Medicare and Medicaid Programs; OBRA '87 Conforming Amendments

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule with comment period.

SUMMARY: These regulations amend certain sections of Medicare and Medicaid rules to reflect 15 self-executing provisions of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) and changes made by sections 102, 103, and 211(b) of the Medicare Catastrophic Coverage Act of 1988 (MCCA), section 608(d)(3)(G) of the Family Support Act of 1988 (Pub. L. 100-485), and sections 6113 and 6301 of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89). They also clarify related rules.

The amendments are needed to make HCFA rules consistent with current provisions of law and to ensure that users of the regulations are not confused by outdated provisions or unclear language. This document also makes technical amendments, primarily to correct internal cross-references, make nomenclature changes, and revise an outdated definition.

DATES:

Effective date: These regulations are effective April 1, 1991.

Comment date: We will consider comments received by April 30, 1991.

ADDRESSES: Mail comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BERC-484-FC, P.O. Box 26676, Baltimore, Maryland 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Ave., SW., Washington, DC

or

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

In commenting, please refer to file code BERC-484-FC. Comments received timely will be available for public inspection as they are received, beginning approximately three weeks after publication of this document, in room 309-G of the Department's offices at 200 Independence Ave., SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: 202-245-7890).

FOR FURTHER INFORMATION CONTACT: Luisa V. Iglesias (202) 245-0383.

SUPPLEMENTARY INFORMATION: Of the 15 provisions noted under SUMMARY, seven affect the Medicare program, and eight, the Medicaid program. Of the seven Medicare provisions, 3 expand coverage of services, and the other four—

- Make the Part B deductibles and coinsurance applicable to ambulatory surgical center (ASC) physician services.
- Remove the requirement, that as a condition for a hospital to participate in Medicare, hospital inpatients other than those who are Medicare beneficiaries must be "under the care of a physician";
- Extend, for one more year, the basis for computing the supplementary medical insurance (SMI) premiums and the "hold harmless" provision applicable when there is no cost-of-living increase in social security monthly benefits; and
- Change the method for determining payment for hospital outpatient radiology services and other diagnostic procedures.

Of the eight provisions that affect Medicaid, two expand coverage of services, three deal with waivers of the State plan requirements that are set forth in section 1902 of the Act, one requires disregard of certain supplemental security income (SSI) benefits for beneficiaries in institutions, and one pertains to organ transplant procedures. The eighth provision amends title XVI of the Act with respect to monthly SSI payments to beneficiaries in medical institutions.

Sections 103 and 211 of the MCCA affect the determination of Medicare Part A and Part B premiums, and the date for promulgation of the Part A premium.

The changes we have made in the rules, to reflect these self-executing provisions of the law and to clarify other related regulations, are discussed below. References to "the Act" are to the Social Security Act. Sections without specific statutory citation are sections of OBRA '87.

I. Expansion of Medicare Coverage

A. Services of Podiatrists

1. Statutory Provision

Section 4039(b) amends paragraph (3) of section 1861(r) of the Act (definition of physician) to remove the requirement that the activities of a doctor of podiatric medicine "be consistent with the policy of the institution with respect to which he performs them" for purposes of the provisions of the Act that pertain to utilization review, home health services, outpatient physical therapy, and certification by a physician as to a patient's need for care.

2. Changes in the Regulations

a. *To reflect changes in the law.* This section required us to remove all provisions stating that a podiatrist's activities must be "consistent with the policy of the institution * * *" which appeared in §§ 409.42(d), 424.11(e), 424.22(a), and 424.24(c). (Previous §§ 405.1625, 405.1633, and 405.1634 were redesignated as §§ 424.11, 424.22, and 424.24 by final rules published on March 2, 1988 at 43 FR 6629.) The revised rules specify that a doctor of podiatric medicine may perform only those plan of treatment functions that are consistent with the functions he or she is authorized to perform under State law.

b. *Technical and editorial revisions of pacemaker rules.* In amending part 409, we noted that the rules on cardiac pacemakers and pacemaker leads contained repetition and unclear cross-references. In order to improve readability and ease of comprehension, we revised §§ 409.19 and 410.64 to provide a more logical organization, clarify cross-references, and simplify presentation. No substantive change is intended.

B. Outpatient Psychiatric Services

1. Statutory Provisions

Sections 4070 (a)(1) and (c)(1) of OBRA '87 amended section 1833(d) of the Act to increase the dollar limit for expenses incurred during a calendar year for outpatient psychiatric treatment from $312.50 to $562.50 for 1988, and to $1,375 for subsequent calendar years. Section 6113 of OBRA '89 further amended section 1833(d) of the Act to remove the dollar limit but retain the 62½ percent limit, to be applied to "incurred expenses".

2. Changes in the Regulations

The provisions discussed are above reflected in changes to §§ 410.152 and 410.155.

C. Comprehensive Outpatient Rehabilitation Facility (CORF) Services

1. Statutory Provisions

Section 4078 amends section 1862(cc) of the Act to provide that Medicare Part B may pay for physical therapy,

occupational therapy, and speech pathology services furnished by a CORF outside its own premises if—

- The plan of treatment requirement is met; and
- The services are not otherwise paid for under Medicare.

Under previous law, all CORF services (except a single home visit if necessary to evaluate the impact of the home environment on the rehabilitation goals) had to be furnished on the premises of the CORF.

2. Changes in the Regulations

To reflect the section 4078 provision, we have amended §§ 410.105(b) and 485.58.

II. Medicare: Miscellaneous Changes

A. "Under the Care of a Physician"

1. Statutory Provision

Section 1861(e) of the Act sets forth the conditions an institution must meet in order to participate in Medicare as a hospital. One of those conditions, which has been in effect since the beginning of the program, is that the institution have a requirement that each inpatient be under the care of a physician. Section 4009(f) amends section 1861(e)(4) to make that requirement applicable only to patients who are Medicare beneficiaries.

Change in the Regulation

This amendment required a change in § 482.12 of the conditions of participation for hospitals.

B. Medicare Premiums

1. Statutory Provisions

a. *Medicare Part A premiums.* Section 103 of the MCCA amends section 1818 of the Act to change the promulgation date and the formula for computing the monthly premium for those individuals who can become entitled to Medicare Part A only by paying a premium.

b. *Part B premiums.* The provision for making the SMI premium equal to 50 percent of the actuarial rate for the aged, that is, 50 percent of the estimated expenditures for services furnished to enrollees age 65 and over (section 1839(e) of the Act) was extended through 1989 by section 4080 of OBRA '87, and through 1990 by section 6301 of OBRA '89.

c. *Hold harmless provision.* The "hold harmless" provision limits the premium increase when there is no cost-of-living increase in social security monthly benefits (section 1839(f) of the Act). This provision was extended for one more year by section 4080 of OBRA '87, and made permanent by section 211(b) of the MCCA.

Under this provision, for individuals who are eligible for Social Security cash benefits for both November and December of a calendar year, there are limits on premium increases. The Part B premiums of those individuals cannot be increased to the point where, because of that increase, the Social Security cash benefit paid for December (the check received in January) is less than the benefit paid for November (the check received in December).

In amending section 1839(f), of the Act, section 211(b) changed "monthly benefit" to "amount of benefits payable". "Monthly benefit" had always been interpreted to mean the amount to which the beneficiary was entitled, regardless of how much was actually paid. The change to "amount payable" permits application of the hold harmless provision even if the payable benefit is also reduced because of government pension offset or workers' compensation payments.

2. Changes in the Regulations

In order to avoid confusion, the section 1818 changes made by the MCCA and the section 1839 changes made by the three cited laws are reflected in these final regulations through amendments to §§ 406.22 and 408.20, respectively.

C. Deductibles and Coinsurance: ASC Services

1. Statutory Provisions

Section 9343(e) of OBRA '86, as amended by section 4085(i)(21)(D) of OBRA '87, amended section 1833 (a) and (b) of the Act to rescind the exemption of ASC facility services from the Part B annual deductible and coinsurance. OBRA '86 did not specify an effective date for this provision. However, on the basis of congressional advice, we determined that the intent was to make the provision effective for services furnished on or after July 1, 1987.

Section 4054 of OBRA '87 was later renumbered 4055 because of duplication of 4052. This section, as amended by section 411(f)(12) of the MCCA, amended sections 1833 (a) and (b) of the Act to make the Part B deductible and coinsurance provisions applicable to ASC physician services, that is, to physician services performed (in an ASC or in a hospital on an outpatient basis) in connection with surgical procedures approved for reimbursement in ASCs. This change is effective for services furnished on or after April 1, 1988.

2. Changes in the Regulations

In order to reflect both the OBRA '86 and the OBRA '87 provisions, and to clarify some confusing aspects of the rules that pertain to ASC services, we have amended §§ 410.152, 410.155 and 410.160 and made the following changes in Part 416:

a. Designated the sections under 5 subparts instead of 3 to facilitate reference to particular aspects.

b. In Subpart A—

- Revised § 416.1 to provide a single comprehensive "Basis and scope" section applicable to the whole part.
- Corrected cross reference in § 416.2.
- Removed § 416.3, as inconsistent with current law, which makes the deductible and coinsurance provisions applicable to ASC services.

c. In subpart B—

Revised the heading to reflect the fact that the "conditions for coverage" are being designated under a new subpart C.

- Removed § 416.20 as duplicative of revised § 416.1.
- Revised § 416.25 and added a new § 416.26 to separate the basic requirements from the procedures for qualifying to participate in Medicare as an ASC.
- Revised § 416.30 to reflect the changes in the deductible and coinsurance provisions of the law, to conform paragraph (f) to the changes being made in § 416.120, as discussed later in this preamble, to change "prospectively" to "next" in paragraph (f)(1) to make clear when the agreement is effective, and to correct internal cross-references.
- In § 416.35, changed future tense to present indicative for consistency with the rest of these rules.
- Moved the content of § 416.39 (deeming of compliance) to the new § 416.26, since "deeming" is one way to qualify to participate as an ASC.
- Designated the "scope of benefits" provisions under a new subpart D, and the "payment" provisions under a new subpart E.

d. In the newly designated subpart D, revised §§ 416.60 and 416.61—

- To eliminate repetition and provide paragraph headings to guide the reader;
- Make clear that, although payment differs depending on where the services are furnished, the scope is the same;
- Reflect the fact that the provisions apply not just to ASC services but also to services furnished in hospital outpatient departments; and
- To specify that intra-ocular lenses are covered.

e. In the redesignated subpart E—

• Removed § 416.100 as duplicative of revised § 416.1.

• Removed § 416.110 as inconsistent with current law.

• Revised § 416.120 as follows:

a. To remove paragraph (b) because the HAASC classification, originally established to make clear that a hospital component furnishing ambulatory surgery could be owned and operated as part of the hospital, does not represent a valid distinction. The fact is that all Medicare participating ASCs, regardless of whether they are "independent" or owned by a hospital, must meet the same participation requirements and are paid in the same manner. A hospital component that furnishes ambulatory surgical services may be considered by the hospital to be part of its outpatient department or a separate entity. If the component is considered to be part of the hospital outpatient department, the ambulatory surgical services are covered and paid for as hospital outpatient services. If the component is considered a separate entity, it must be certified as an ASC and is paid under the ASC rules.

b. To clarify policy on payment for multiple surgical procedures performed at a single operative session (paragraph (c)).

• Made minor editorial changes in § 416.125.

• In §§ 416.130 and 416.140, changed future tense to present indicative for consistency with the rest of these rules, and made clarifying editorial changes in § 416.140.

D. Application of Blood Deductible

1. Statutory Provisions

a. Section 102 of the MCCA amends section 1813(a)(2) of the Act to provide that the Medicare Part A blood deductible shall be reduced to the extent that a blood deductible has been applied under Medicare Part B.

b. Section 608(d)(3)(G) of the Family Support Act of 1988, enacted October 13, 1988, amends section 104 of the MCCA to add a new subsection (d)(7) which, in turn, amends section 1833(b) of the Act to provide that the Part B blood deductible shall be reduced to the extent that a blood deductible has been applied under Medicare Part A.

2. Changes in the Regulations

a. In § 409.87, we have revised paragraphs (a)(3) and (a)(6).

b. In § 410.161, we have made a conforming technical amendment, which appears at the end of the rules text with other technical amendments.

c. In part 489, we have revised section 489.31.

E. Partial Hospitalization Services

1. Statutory Provisions

Section 4070(b), as amended by section 411(h)(1)(B) of the MCCA, amends the definitions section of the Medicare title as follows:

a. Amends section 1861(s)(2)(B) of the Act to provide that partial hospitalization services incident to physician services, furnished by a hospital to its outpatients, are covered as medical and other health services.

b. Adds to section 1861 a new subsection (ff) to—

1. Define "partial hospitalization services" as a program that is furnished by a hospital to its outpatients and is a distinct and organized intensive ambulatory treatment program offering less than 24-hour-daily care;

2. Specify eight services included in partial hospitalization services;

3. Provide that the Secretary may add other services, with the exception of meals and transportation;

4. Require that the services be—

• Reasonable and necessary for the diagnosis or active treatment of the individual's condition;

• Reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization; and

• Furnished pursuant to such guidelines relating to frequency and duration of services as are established by regulation, taking into account accepted norms of medical practice and the reasonable expectation of patient improvement; and

5. Require that the services be prescribed by a physician under a written individualized plan of treatment that (1) is established and periodically reviewed by a physician, in consultation with appropriate staff participating in the program and (2) sets forth the physician's diagnosis, the type, amount, duration, and frequency of the services and the goals for treatment under the plan.

At this time we do not consider it desirable to establish by regulation specific limits on the frequency and duration of these services. We believe that the physician who establishes and reviews the plan of treatment can best determine what is necessary and appropriate for each patient. Accordingly, the guidelines in these rules make the physician responsible for specifying how often and for how long partial hospitalization services are to be furnished to each patient. If experience indicates the need to regulate this aspect, we would follow the notice and opportunity for comment procedures. In the meantime, we plan to seek a technical amendment that would authorize but not require the Secretary to issue additional guidelines. Section 4070(b) also amends section 1835(a)(2) by adding a new subparagraph (F) to require that, as a condition for Medicare payment, a physician certify that—

a. The individual would require inpatient psychiatric care in the absence of partial hospitalization services;

b. An individualized written plan of care has been established and is reviewed periodically by a physician; and

c. The services are or were furnished while the individual is or was under the care of a physician.

(Physician certification is not required for any other "incident to" services.)

2. Changes in the Regulations

a. In § 410.2 we have inserted a definition of "partial hospitalization services".

b. In § 410.10 we have made a conforming change in paragraph (c).

c. In § 410.27, we have added a new paragraph (d) to specify the conditions for coverage of these services. This paragraph would be amended later if it is found necessary to establish limits on the frequency and duration of these services.

d. In § 424.24, we have made conforming changes in paragraphs (a) and (b) and added a new paragraph (e) to set forth the physician certification and plan of treatment requirements for these services.

F. Delayed Action Amendment

Section 4033 amends section 226(f) of the Act to permit months from a previous period of disability benefit entitlement to be counted in determining when Medicare Part A may begin for an individual who becomes disabled more than 60 months (84 months if previous entitlement was as a disabled child, widow, or widower) after the month in which the previous period of disability benefit entitlement ended. The earlier months of disability may be counted only if the physical or mental impairment that is the basis for the current disability is the same as or directly related to the impairment that was the basis for the previous period of entitlement to disability benefits.

The amendment applies only if the previous period of disability benefit entitlement ended on or after February 21, 1988. This, in conjunction with the requirement that the previous period must have ended more than 60 or 84 months before the onset of the current disability, means that the earliest anyone could qualify for Medicare Part

A under the section 4033 amendment is March 1993, or March 1995 if previous entitlement was as a disabled child, widow, or widower.

We have made no changes in the regulations because we anticipate that further changes will be made in the law before 1993.

III. Expansion of Medicaid Coverage

A. Services of Dentists

1. Statutory Provision

Section 4103 amends section 1905(a)(5) of the Act to require the State Medicaid plan to include medical and surgical services furnished by a dentist, if under State law those services may be performed either by a doctor of medicine or a doctor of dental surgery or dental medicine, and would be considered physicians' services if furnished by a physician.

The requirement is effective for calendar quarters beginning on or after January 1, 1988. However, the law makes special provision for States that must seek legislative action (for purposes other than appropriation of funds) before they can amend their State plans. In those circumstances, the State plan would not be considered to be out of compliance with the title XIX requirements until the first day of the first quarter that begins after the close of the first regular legislative session that begins after enactment of the provision (December 22, 1987).

2. Changes in the Regulations

This additional Medicaid coverage is shown in revised § 440.50.

B. Clinic Services

1. Statutory Provision

Section 4105 amends the definition of "clinic services" (section 1905(a)(9) of the Act) to clarify that the term includes services furnished outside the clinic, by clinic personnel, to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address.

2. Changes in the Regulations

This provision required that we amend § 440.90, which defines "clinic services".

We are amending the clinic definition to reflect the recent legislative change, and to clarify that this represents an exception to the general coverage requirement for services to be furnished on the premises of the clinic. Clinic services have always been limited to people who go to the clinic (or a satellite location) and get the services onsite. In regulations this result was achieved by virtue of defining the services as furnished "to outpatients." The outpatient definition (§ 440.2) originally was written in terms of a patient who is receiving services "at an organized medical facility." In BERC-513-F, a regulation which grew out of the regulatory reform effort, we revised the outpatient definition from a patient receiving services "at" an organized medical facility to a patient "of" an organized medical facility (52 FR 47934, December 17, 1987). This change had the unintended effect of creating confusion in the context of the clinic benefit over whether services still had to be furnished on the premises of a clinic in order to be covered under the clinic benefit. It was never our intention to rescind the onsite requirement, and we are not aware of any changes made by States in clinic coverage as a result of the revision to the outpatient definition. Accordingly, we are correcting our error in this regulation. We would note that, in enacting the recent provision for coverage of clinic services for homeless individuals, Congress has now established an explicit exception to the normal requirement that clinic services be furnished onsite in order to be covered, thus ratifying the current requirement that other services must be furnished onsite.

IV. Medicaid: Waivers of State Plan Requirements

A. Freedom of Choice of Providers of Family Planning Services

1. Statutory Provisions

Section 1915(b) of the Act, which authorizes the Secretary to waive State plan requirements set forth in section 1902 of the Act, specifies that no such waiver may restrict an individual's freedom of choice of providers of family planning services.

Subsequent amendments to the Act have retained or extended this rule, as shown below.

a. Section 9508(a) of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 amended section 1915 of the Act to provide, effective April 7, 1986, that a State—

- Could furnish case-management services as medical assistance, with a waiver of the State-wideness and comparability of services requirements; but
- Could not, with respect to an individual receiving case-management services, restrict that individual's freedom of choice of providers of family planning services.

b. OBRA '87 sections 4113 (c)(1) and (c)(2) amend sections 1902(a)(23) and 1902(e)(2)(A) of the Act, respectively, to apply this rule effective for services furnished on or after July 1, 1988.

The amendment to section 1902(a)(23) of the Act provides that a Medicaid recipient enrolled in a primary care case-management system, an HMO, or a similar entity, may not be restricted in his or her freedom of choice of providers of family planning services.

The amendment to section 1902(e)(2)(A) of the Act excludes family planning services from the restriction imposed on HMO enrollees who lose Medicaid eligibility but are deemed to continue to be eligible for the remainder of a minimum HMO enrollment period. The restriction is that the enrollee is eligible only for services furnished by the HMO. Under the amendment, the enrollee is free to seek family planning services from any qualified provider.

2. Changes in the Regulations

These provisions required us to amend §§ 431.51 and 435.212. In § 431.51(b)(1), we have added language to counteract a misunderstanding that has arisen in the past: freedom of choice does not obligate a Medicaid provider to furnish services to every recipient. Within specified limits, a recipient may seek to obtain services from any qualified provider, but the provider determines whether to furnish services to the particular recipient. This is consistent with the language of § 1902(a)(23) of the Act; "* * * who undertakes to provide him such services."

B. Extension of Special Waivers to the Northern Mariana Islands

1. Statutory Provision

Section 4116 amends section 1902(j) of the Act to extend the waiver provisions of that section to the Northern Mariana Islands.

2. Changes in the Regulations

In § 431.56, we have added "Northern Mariana Islands" where appropriate.

C. Time Allowed for Decision on Waiver Requests

1. Statutory Provision

Section 4118(l) amends section 1915(h) of the Act to provide that—

- A request for continuation of a section 1915 waiver shall be deemed granted unless, within 90 days, the Secretary denies the request or requests additional information; and
- If the Secretary requests additional information, the 90 days allowed for the Secretary to reach a decision begin anew when he or she receives the additional information. This is

consistent with the time frames already applicable to initial waiver requests.

2. Changes in the Regulations

This provision highlighted the need to set forth the procedures that HCFA follows in processing waiver requests. This need is met by adding a new § 430.25, in which paragraph (f) reflects the amendment discussed above. Except for paragraph (f), the new § 430.25 is merely a codification of practice that has long been in effect but had not been set forth in regulations.

We also noted that Subpart B of Part 431 (which deals with exceptions and waivers) needed clarification and updating. The specific changes in Subpart B include the following:

a. A new § 431.40 to set forth the basis and scope of the subpart.

b. Revision of §§ 431.50(c) and 431.51 for consistency in dealing with "exceptions".

c. Removal of outdated content:

• References to title IV–E children are removed from § 431.52 (Payment for out-of-State services) because, under section 1902(a) of the Act, the State where these children reside is responsible for providing their Medicaid services.

• References to section 1903(m) waivers are removed from § 431.55 because those waivers had to be in place before August 10, 1982 and could not be renewed.

• The presumed exception that would permit a State to limit payment for rural health clinic services to services provided by a rural health clinic (paragraph (c) of § 431.54) is removed because, by definition (§ 440.20(b)), "rural health clinic services" are already limited to services "furnished by a rural health clinic".

d. Editorial revisions that clarify the rules and follow the general style conventions of HCFA rules, such as—

• Reduction of overlong sentences (70 to 100 words) in § 431.55(c) and (e).

• Use of active voice and present tense rather than passive voice and future tense.

• More designated items and more headings to guide the reader.

V. Medicaid: Post-Eligibility Treatment of Income of Individuals in Institutions

1. Background

a. Title XIX of the Act and the Medicaid regulations provide for mandatory and optional disregards of certain amounts of income of individuals who are in institutions. These disregards help to determine how much of a recipient's income is applied to the cost of institutional care.

b. Final regulations published on February 8, 1988 (53 FR 3586), to be effective April 8, 1988, amended Medicaid rules with the intent of making optional for States what had previously been required: The disregard of income needed to cover expenses incurred for necessary medical and remedial care recognized under State law but not included in the State Medicaid plan.

c. The statutory amendments discussed below made it necessary to restore the requirement that the February 8 rules would have made optional, and to make other changes in the regulations pertaining to treatment of income of individuals in institutions.

2. Statutory Provisions

a. Section 303(d) of the Medicare Catastrophic Coverage Act of 1988 (Pub. L. 100–360, commonly referred to as the MCCA) amended section 1902 of the Act to add a new subsection (r), which was redesignated as (r)(1) by section 303(e)(5) of the same law. Subsection (r)(1) requires disregard of income needed for the type of expenses noted in 1. b. above. Since the change in the law was made effective on April 8, 1988, the result is that the February 8 provision never went into effect and the previous disregard requirement continues without interruption. (Section 303(a)(1)(B) of the MCCA added to the Act a new section 1924 that also affects posteligibility treatment of the income and resources of an institutionalized spouse and of the spouse who remains in the community. The new provisions are being implemented by States under general instructions and will be codified in the CFR through other regulations identified as BPD–609–P.)

b. Section 9115 of OBRA '87 amends section 1611(e)(1) of the Act to provide, in subparagraph (G), that full SSI and SSP benefits be continued for up to three months after the beneficiary enters a medical institution if specified conditions are met. Section 9115 also amends section 1902(o) of the Act (which already required disregard of any SSI and SSP benefits continued under section 1611(e)(1)(E) of the Act) to require that, in determining the amount of any post-eligibility contribution by the individual to the cost of care and services, the full SSI and SSP benefits continued under section 1611(e)(1)(G) of the Act also be disregarded.

c. Section 9119 amends title XVI (SSI) of the Act to increase the monthly SSI payment to recipients in medical institutions from $25 to $30 for individuals, and from $50 to $60 for couples.

As enacted, section 9119 did not amend the Medicaid law. However, section 411(n)(3) of Pub. L. 100–360 adds to section 1902 a new subsection (q) which—

• Requires Medicaid personal needs allowances of at least $30 for an individual and $60 for a couple; and

• Makes the amendment effective for Medicaid payments made on or after July 1, 1988.

Previous regulations specified minimum personal allowance amounts for the 50 States, the District of Columbia, American Samoa, and the Northern Mariana Islands, but not for Puerto Rico, the Virgin Islands, and Guam. Now that minimum amounts are required by law, they must be applied also to the latter three jurisdictions. Disregard of continued SSI or SSP payments does not apply because the SSI program is not in effect in those three jurisdictions.

3. Changes in the Regulations

a. Sections 435.725 and 435.733 of the Medicaid rules are revised to provide that, in determining the amount that a recipient in a medical institution will contribute to the cost of institutional care, the full SSI and SSP benefits continued under sections 1611(e)(1) (E) and (G) of the Act must be disregarded.

b. Sections 435.725, 435.733, 435.832, and 436.832 of the Medicaid rules are revised—

• To require a minimum personal needs allowance of $30 for individuals and $60 for couples; and

• To conform to section 1902(r)(1) by revising the paragraphs that deal with expenses incurred for necessary medical and remedial care recognized under State law but not included in the State Medicaid plan, to restore the requirement that was in effect before publication of the February 8 rules.

VI. Medicaid—Requirements for Organ Transplant Procedures

A. Statutory Provisions

COBRA section 9507(a) amended section 1903(i) of the Act to add a new paragraph (1) under which FFP would be denied for organ transplant procedures after December 1986 unless—

1. The State plan provides for written standards for coverage of those procedures; and

2. Those standards provide that—

• Similarly situated individuals are treated alike; and

• Any restriction on the facilities or practitioners that may provide such procedures is consistent with the accessibility of high quality care to individuals eligible for the procedures under the plan.

OBRA '87 section 4118(d), through a technical amendment made effective as though it had been enacted with COBRA, added, at the end of the paragraph (i):

> Nothing in paragraph (1) shall be construed as permitting a State to provide services under its plan under this title that are not reasonable in amount, duration, and scope to achieve their purpose.

B. Changes in the Regulations

Section 441.10 has been amended and a new § 441.35 has been added to reflect both of the statutory amendments.

VII. Medicare—Payment for Hospital Outpatient Radiology and Other Diagnostic Services

1. Statutory Provisions

Part B of the Medicare program covers medical and other health services as defined in section 1861(s) of the Act. The method for determining payment for covered radiology services and other diagnostic procedures furnished by a hospital on an outpatient basis has changed as a result of section 4066 of OBRA '87. Specifically, section 4066 (which was subsequently amended by section 411(g)(4) of the Medicare Catastrophic Coverage Act of 1988) amends section 1833 of the Act to add a new subparagraph (a)(2)(E) and a new subsection (n) that change the basis for Medicare payment—

- For outpatient hospital radiology services furnished on or after October 1, 1988; and
- For certain other diagnostic procedures (as defined by the Secretary) furnished on or after October 1, 1989.

2. Changes in the Regulations

The new method determines payment to the hospital partly on the basis of the prevailing charges in the locality for the same services furnished by physicians in their offices. The law provides that the prevailing charge portion of the radiology payment is computed on the basis of "62 percent * * * of 80 percent of the prevailing charge * * * for participating physicians for the same services * * *". The 62 percent adjustment is necessary to exclude the professional component of the prevailing charge, and the 80 percent adjustment excludes beneficiary coinsurance amounts. The order of the computation as stated in the law does not properly take into account the Part B annual deductible which must be subtracted from the technical component of the professional charge before the coinsurance adjustment is made. We do not believe that Congress intended to change the way that Part B deductible and coinsurance are applied in determining Medicare payment. We have made this clear in a new § 413.122 which conforms to current billing practices for outpatient radiology and for other diagnostic procedures. The section 4066 changes also required us to amend § 413.13(c) to specify that these costs are aggregated and treated separately from all other hospital costs.

VIII. Medicare—Physician Certification of Need for Services

As noted above, final rules published on March 2, 1988 redesignated subpart P of part 405 of the Medicare rules under a new part 424—Conditions for Medicare Payment. We requested comments from any reader who believed that, in the process of simplifying, clarifying, and redesignating the old rules we had unintentionally made substantive changes not discussed in the preamble.

We received two comments (from a national professional association and a law firm) indicating that the following change was substantive.

Previous § 405.1625 stated:

> (a) The health insurance program recognizes the physician as the key figure in determining utilization of health services; the physician decides upon admission to a hospital, orders tests, drugs, and treatments, and determines the length of stay.

New § 424.10 reads:

> (a) *Purpose.* The physician has a major role in determining utilization of health services furnished by providers. The physician decides upon admissions, orders tests, drugs and treatments, and determines the length of stay.

In the revised section, using "major role" rather than "key figure" was not intended as a substantive change. The second clause, which provides the "evidence" of the physician's importance, the things he or she does that influence utilization, was retained unchanged. However, in order to ensure that others do not misinterpret the change as reducing the physician's importance in determining utilization of services, we are restoring the term "key figure" in § 424.10. This change appears among the technical amendments at the end of the rules text.

IX. Medicare and Medicaid: Handling of a New Term

"Conditions of participation" is the term that has long been used in connection with providers that participate or seek to participate in Medicare. In some cases, the same conditions apply to participation in Medicaid.

Final rules published on February 2, 1989 (54 FR 5316) amended part 483 (established by a final rule published on June 3, 1988 at 53 FR 20448) to add a new subpart B. Subpart B redesignated and revised the Medicare rules previously contained in subpart K of part 405 (Conditions of Participation; Skilled Nursing Facilities (SNFs)) and the Medicaid rules in subparts D through F of part 442 (Requirements for SNFs and Intermediate Care Facilities (ICFs)), and standards for ICFs other than ICFs for the Mentally Retarded (ICFs/MR).

The rules published on February 2, 1989 used the term "requirements for participation" in lieu of "conditions of participation".

This new terminology would require us to identify all the Medicare and Medicaid rules that refer to "conditions of participation" in order to insert "requirement for participation" where appropriate.

We have chosen, as a simpler way to take care of current and future needs in this area, to define "conditions of participation" to include "requirements for participation", as the latter term is used in part 483. The definition is inserted in § 400.200, and appears at the end of the text with other technical and conforming amendments.

X. Technical Amendments

The technical amendments that appear under part 430 and at the end of the text are necessary to—

- Make explicit what was implicit in the language of 45 CFR 201.3(g) before it was redesignated as 42 CFR 430.20 by final rules published on September 21, 1988 at 53 FR 36573. The § 201.3(g) reference to "additional assistance" (to be provided under an amendment to the State Medicaid plan) means not only additional services, but also increased payment for services already included in the plan.
- Explain acronyms and abbreviations that are used frequently in the HCFA rules.
- Correct references to sections of the law and regulations that have been redesignated or removed, and to organizations that have changed their names.
- Make clear the relationship between "*conditions of participation*" and "*requirements for participation*", and between "*condition level*" deficiencies, and deficiencies with respect to "*level A requirements*".
- Make clear, by amending parts 410 and 424, that physician certification of need for medical and other health services is required only if those part B services are furnished by providers and, accordingly, is not required for home dialysis support services furnished by

an ESRD facility. (The plan of treatment requirements for home dialysis support services are set forth in § 410.52(b) of the Medicare rules.)

• Conform the definition of "institution for mental diseases" (as it appears in §§ 435.1009 and 440.140(a)(2)) to the clarification made by section 411(k)(14) of Pub. L. 100–360.

• Conform an appeals provision (§ 498.3(d)(3)) to the pertinent provider agreement rule (§ 489.12).

XI. Waiver of Proposed Rulemaking

These rules conform HCFA regulations to 14 self-executing amendments to the Medicare and Medicaid laws (titles XVIII and XIX of the Social Security Act) and one amendment to the SSI law (title XVI of the Act).

With two minor exceptions, the amendments to the Act are so specific and detailed that they leave no room for alternative interpretations or implementation. The two exceptions are in the amendments made by sections 4066 and 4070(b).

Section 4066 Amendments

Amended sections 1833(a)(2)(E) and 1833(n) of the Act are specific as to the changes in the method for computing payment for hospital outpatient radiology services. However, the Secretary is to define the "other outpatient diagnostic procedures" that are subject to those changed computation methods. We plan to publish the definition in the Federal Register.

Added section 1861(ff) of the Act requires us to establish guidelines as to the frequency and duration of partial hospitalization services. In these rules we are adopting guidelines under which we delegate responsibility to the physician who establishes and reviews the plan of treatment. We believe that the physician is best able to determine the frequency and duration that is necessary and appropriate for each patient. If experience indicates the need for Federal limits, we will publish additional guidelines as a notice of proposed rulemaking.

The editorial changes and technical amendments to other related regulations have no substantive effect, and the new § 430.25 simply codifies long-standing practice. Accordingly, we find that there is good cause to dispense with proposed rulemaking.

However, as previously indicated, we will consider timely comments from anyone who believes that, in the conforming amendments we have misinterpreted the intent of the law, or in the technical and editorial changes, we have unintentionally made substantive changes other than those discussed in this preamble.

Although we cannot respond to comments individually, if we change these rules as a result of comments, we will discuss all comments in the preamble to the revised rules.

XII. Regulatory Impact Statement

Executive Order 12291 requires us to prepare and publish a regulatory impact analysis for any regulation that is likely to have an annual impact of $100 million or more, cause a major increase in costs or prices, or meet other thresholds specified in section 1(b) of the order.

In addition, consistent with the Regulatory Flexibility Act (RFA) and section 1102(b) of the Social Security Act, we prepare a regulatory flexibility analysis for each rule, unless the Secretary certifies that the particular rule will not have a significant economic impact on a substantial number of small entities, or a significant impact on the operation of a substantial number of small rural hospitals.

The RFA defines "small entity" as a small business, a nonprofit enterprise, or a governmental jurisdiction (such as a county, city, or township) with a population of less than 50,000. We also consider all providers and suppliers of services to be small entities. For purposes of section 1102(b) of the Act, we define small rural hospital as a hospital that has fewer than 50 beds, and is located anywhere but in a metropolitan statistical area.

These regulations amend the HCFA rules to reflect changes made by specified provisions of the four laws identified at the beginning of this preamble. Since the provisions are already in effect, publication of these conforming amendments to the HCFA rules will have no additional impact, but will simply ensure that the rules reflect current statutory requirements.

Accordingly—

• We have determined that these rules will not have a significant impact on the general economy nor do they meet any of the other threshold criteria contained in Executive Order 12291. Therefore, a regulatory impact analysis is not required.

• We have determined, and the Secretary certifies, that these rules will not have a significant economic impact on a substantial number of small entities, and will not significantly affect the operation of a substantial number of small rural hospitals. Therefore, a regulatory flexibility analysis is not required.

Paperwork Reduction Act

These regulations contain no new information collection requirements subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1980.

List of Subjects

42 CFR Part 400

Grant programs—health, Health facilities, Health maintenance organizations (HMO), Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Nursing homes, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 406

Health facilities, Kidney diseases, Medicare.

42 CFR Part 408

Health facilities, Kidney diseases, Medicare.

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, X-rays.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 417

Administrative practice and procedures, Health maintenance organization (HMO), Medicare, Reporting and recordkeeping requirements.

42 CFR Part 424

Assignment of benefits, Physician certification, Claims for payment, Emergency services, Plan of treatment.

42 CFR Part 430

Grant programs—health, Medicaid.

42 CFR Part 431

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 435

Aid to Families with Dependent Children, Grant programs—health, Medicaid, Reporting and recordkeeping requirements, Supplemental Security Income (SSI), Wages.

42 CFR Part 436

Aid to Families with Dependent Children, Grant programs—health, Guam, Medicaid, Puerto Rico, Supplemental Security Income (SSI), Virgin Islands.

42 CFR Part 440

Grant programs—health, Medicaid.

42 CFR Part 441

Family planning, Grant programs—health, Infants and children, Medicaid, Penalties, Prescription drugs, Reporting and recordkeeping requirements.

42 CFR Part 447

Accounting, Administrative practice and procedure, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

42 CFR Part 455

Fraud, Grant programs—health, Health facilities, Health professions, Investigations, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 482

Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare.

42 CFR Part 491

Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural areas.

42 CFR Part 498

Administrative practice and procedure, Appeals, Medicare practitioners, providers and suppliers.

42 CFR chapter IV is amended as set forth below:

A. Part 406.

PART 406—HOSPITAL INSURANCE ELIGIBILITY AND ENTITLEMENT

1. The authority citation continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart B—Hospital Insurance Without Monthly Premiums

2. The heading of subpart B is revised to read as set forth below.

3. Section 406.22 is amended by revising paragraphs (a) and (b) to read as follows:

§ 406.22 Monthly premiums.

(a) *Promulgation and effective date.* Beginning with 1984, premiums are promulgated each September, effective for the succeeding calendar year.

(b) *Premium amounts.* (1) Before July 1974, the monthly premium was $33.

(2) For months after June 1974 and before January 1989, the dollar amount was determined by multiplying $33 by the ratio of next year's inpatient deductible to $76, which was the inpatient deductible determined for 1973. (Because of price controls, the deductible actually charged for 1973 was $72.)

(3) Beginning with 1989, the monthly premium is equal to one twelfth of the per capita amount that the Secretary estimates will be payable under part A for services and administrative costs with respect to individuals age 65 and over who are entitled to part A benefits throughout the year for which the premium applies.

(4) The amount determined by the formula is rounded to the nearest multiple of $1 (50¢ is rounded to the next higher dollar).

* * * * *

B. Part 408.

PART 408—PREMIUMS FOR SUPPLEMENTARY MEDICAL INSURANCE

1. The authority citation continues to read as follows:

Authority: Secs. 1102, 1818, 1837–1840, 1843, 1871, and 1881(d) of the Social Security Act (42 U.S.C. 1302, 1395i–2, 1395p–1395s, 1395v, 1395hh, and 1395rr(d)), and the Federal Claims Collection Act (31 U.S.C. 3711).

2. Section 408.20 is revised to read as follows:

§ 408.20 Monthly premiums.

(a) *Statutory provisions.* (1) The law established a monthly premium of $3 for the initial period of the program. It also set forth criteria and procedures for the Secretary to follow each December, beginning with December 1968, to determine and promulgate the standard monthly premium for the 12–month period beginning with July of the following year.

(2) The law was amended in 1983 to require that the Secretary promulgate the standard monthly premium in September of that year, and each year thereafter, to be effective for the 12 months beginning with the following January.

(3) The standard monthly premium applies to individuals who enroll during their initial enrollment periods. In other situations, that premium may be increased or decreased as specified in this subpart.

(4) The law was further amended in 1984 to include a temporary "hold harmless" provision (set forth in paragraph (e) of this section), that was subsequently extended and finally made permanent in 1988.

(b) *Criteria and procedures for the period from July 1976 through December 1983, and for periods after December 1990.* (1) For periods from July 1976 through December 1983, the Secretary determined and promulgated as the standard monthly premium (for disabled as well as aged enrollees) the lower of the following:

(i) The actuarial rate for the aged.

(ii) The monthly premium promulgated the previous December for the year beginning July 1, increased by a percentage that is the same as the latest cost-of-living increase in old age insurance benefits that occurred before the current promulgation. (Because of the change in the effective dates of the premium amount (under paragraph (a)(2) of this section), there was no increase in the standard monthly premium for the period July 1983 through December 1983.)

(2) For periods after December 1990, the Secretary determines the standard monthly premium in the manner specified in paragraph (b)(1) of this section, but promulgates it in September, for the following calendar year.

(c) *Premiums for calendar years 1984 through 1990.* For calendar years 1984 through 1990, the standard monthly premium for all enrollees—

(1) Is equal to 50 percent of the actuarial rate for enrollees age 65 or over, that is, is calculated on the basis of 25 percent of program costs without regard to any cost-of-living increase in old age insurance benefits; and

(2) Is promulgated in the preceding September.

(d) *Limitation on increase of standard premium: 1987 and 1988.* If there is no cost-of-living increase in old age or disability benefits for December 1985 or December 1986, the standard monthly premiums for 1987 and 1988 (promulgated in September 1986 and September 1987, respectively) may not be increased.

(e) *Nonstandard premiums for certain cases*—(1) *Basic rule.* A nonstandard

premium may be established in individual cases only if the individual is entitled to old age or disability benefits for the months of November and December, and actually receives the corresponding benefit checks in December and January.

(2) *Special rules: Calendar years 1987 and 1988.* For calendar years 1987 and 1988, the following rules apply:

(i) A nonstandard premium may be established if there is a cost-of-living increase in old age or disability benefits but, because the increase in the standard premium is greater than the cost-of-living increase, the beneficiary would receive a lower cash benefit in January than he or she received in December.

(ii) A nonstandard premium may not be established if the reduction in the individual's benefit would result, in whole or in part, from any circumstance other than the circumstance described in paragraph (e)(2)(i) of this section.

(3) *Special rule: Calendar years after 1988.* (i) Beginning with calendar year 1989, a premium increase greater than the cost-of-living increase is still a prerequisite for a nonstandard premium.

(ii) However, a nonstandard premium is not precluded solely because the cash benefit is further reduced as a result of government pension offset or workers' compensation payment.

(4) *Amount of nonstandard premium.* The nonstandard premium is the greater of the following:

(i) The premium paid for December.

(ii) The standard premium promulgated for January, reduced as necessary to compensate for—

(A) The fact that the cost-of-living increase was less than the increase in the standard premium; or

(B) The further reduction in benefit because of government pension offset or workers' compensation payments.

(5) *Effective dates of nonstandard premium.* A nonstandard premium established under this paragraph (e) continues in effect for the rest of the calendar year even if later there are retroactive adjustments in benefit payments. (The nonstandard premium could be affected by a determination that the individual had not established, or had lost, entitlement to monthly benefits for November or December, or both.)

(6) *Effect of late enrollment or reenrollment.* A nonstandard premium is subject to increase for late enrollment or reenrollment as required under other sections of this subpart. The increase is computed on the basis of the standard premium and added to the nonstandard premium.

C. Part 409.

PART 409—HOSPITAL INSURANCE BENEFITS

1. The authority citation continues to read as follows:

Authority: Secs. 1102, 1812, 1813, 1861, 1862(h), 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395d, 1395e, 1395x, 1395y(h), 1395hh, and 1395rr.

2. Section 409.19 is revised to read as follows:

§ 409.19 Services related to cardiac pacemakers and pacemaker leads.

(a) *Requirement.* (1) Providers that request or receive Medicare payment for the implantation, removal, or replacement of permanent cardiac pacemakers and pacemaker leads must submit to HCFA the information required for the pacemaker registry.

(2) The required information is set forth under 21 CFR part 805 of the FDA regulations and must be submitted in accordance with general instructions issued by HCFA.

(b) *Denial of payment.* If HCFA finds that a provider has failed to comply with paragraph (a) of this section, HCFA will deny payment for the implantation, removal, or replacement of any permanent cardiac pacemaker or pacemaker lead, effective 45 days after sending the provider written notice in accordance with paragraph (c) of this section.

(c) *Notice of denial of payment.* The notice of denial of payment—

(1) States the reasons for the determination;

(2) Grants the provider 45 days from the date of the notice to submit the information or evidence showing that the determination is in error; and

(3) Informs the provider of its right to hearing.

(d) *Right to hearing.* If the denial of payment determination goes into effect at the expiration of the 45-day period, it constitutes an "initial determination" subject to administrative and judicial review under part 498 of this chapter.

3. In § 409.42, paragraph (d) is revised to read as follows:

§ 409.42 Requirements and conditions for home health services.

* * * * *

(d) *Plan of treatment requirements.*[2] The home health services must be furnished under a plan of treatment that is established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine. A doctor of podiatric medicine may establish a plan of treatment only if that is consistent with the functions he or she is authorized to perform under State law.

4. Section 409.87 is amended to revise paragraphs (a)(3) and (a)(6) to read as follows:

§ 409.87 Blood deductible.

(a) General provisions. * * *

3. Medicare does not pay for the first 3 units of whole blood or units of packed red cells that a beneficiary receives, during a benefit period, as an inpatient of a hospital or SNF, or on an outpatient basis under Medicare Part B.

* * * * *

(6) The Part A blood deductible is reduced to the extent that the Part B blood deductible has been applied. For example, if a beneficiary had received one unit under Medicare Part B, and later in the same benefit period received three units under Medicare Part A, Medicare Part A would pay for the third of the latter units. (As specified in § 410.161 of this chapter, the Part B blood deductible is reduced to the extent a blood deductible has been applied under Medicare Part A.)

* * * * *

D. Part 410.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

1. The authority citation continues to read as follows:

Authority: Secs. 1102, 1832, 1835, 1861(r), (s), and (cc), 1871, and 1881 of the Social Security Act (42 U.S.C.) 1302, 1395K, 13951, 1395n, 1395x(r), (s), and (cc), 1395hh, and 1395rr.

§ 410.2 [Amended]

2. Section 410.2 is amended to add the following definition in alphabetical order:

Partial hospitalization services means (a) A distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care and furnishes services that—

(1) Are reasonable and necessary for the diagnosis or active treatment of the individual's condition;

(2) Are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization; and

(3) Include any of the following:

(i) Individual and group therapy with physicians or psychologists or other

[2] Before January 1981, only a doctor of medicine or osteopathy could establish a plan for home health services. A plan of treatment established before July 1981 was acceptable for Medicare Part A payment only if it was established within 14 days after the individual's discharge from a hospital or SNF.

mental health professionals to the extent authorized under State law.

(ii) Occupational therapy requiring the skills of a qualified occupational therapist.

(iii) Services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients.

(iv) Drugs and biological furnished for therapeutic purposes, subject to the limitations specified in § 410.29.

(v) Individualized activity therapies that are not primarily recreational or diversionary.

(vi) Family counseling, the primary purpose of which is treatment of the individual's condition.

(vii) Patient training and education, to the extent the training and educational activities are closely and clearly related to the individual's care and treatment.

(viii) Diagnostic services.

(ix) Other items and services as specified by HCFA, excluding meals and transportation.

3. Section 410.10 is amended to correct the heading, and revise the introductory text, and paragraph (c) to read as follows:

§ 410.10 Medical and other health services: Included services.

Subject to the conditions and limitations specified in this subpart, "medical and other health services" includes the following services:

* * * * *

(c) Services and supplies, including partial hospitalization services, that are incident to physician services and are furnished to outpatients by or under arrangements made by a hospital.

* * * * *

4. Section 410.27 is revised to read as follows:

§ 410.27 Outpatient hospital services and supplies incident to physicians' services: Conditions.

(a) Medicare Part B pays for hospital services and supplies furnished incident to physicians' services to outpatients, including drugs and biologicals that cannot be self-administered, if—

(1) They are furnished—

(i) By or under arrangements made by a participating hospital; and

(ii) As an integral though incidental part of a physician's services; and

(2) In the case of partial hospitalization services, also meet the conditions of paragraph (d) of this section.

(b) Drugs and biologicals are also subject to the limitations specified in § 410.168.

(c) Rules on emergency services furnished to outpatients by nonparticipating hospitals are specified in § 410.168.

(d) Medicare Part B pays for partial hospitalization services if they are—

(1) Prescribed by a physician who certifies and recertifies the need for the services in accordance with subpart B of part 424 of this chapter; and

(2) Furnished under a plan of treatment as required under subpart B of part 424 of this chapter.

5. Section 410.64 is revised to read as follows:

§ 410.64 Services related to cardiac pacemakers and pacemaker leads.

(a) *Requirement.* (1) Physicians or providers that request or receive payment for the implantation, removal, or replacement of permanent cardiac pacemakers and pacemaker leads, must submit to HCFA the information required for the pacemaker registry.

(2) The required information is set forth under 21 CFR part 805 of the FDA regulations and must be submitted in accordance with general instructions issued by HCFA.

(b) *Denial of payment.* If HCFA finds that a physician or provider has failed to comply with paragraph (a) of this section, HCFA will deny payment for the implantation, removal, or replacement of any permanent cardiac pacemaker or pacemaker lead, effective 45 days after sending the physician or provider written notice in accordance with paragraph (c) of this section.

(c) *Notice of denial of payment.* The notice of denial of payment—

(1) States the reasons for the determination;

(2) Grants the physician or provider 45 days from the date of the notice to submit the information or evidence showing that the determination is in error; and

(3) Informs the physician or provider of its right to hearing.

(d) *Right to hearing.* If the denial of payment goes into effect at the expiration of the 45-day period, it constitutes an "initial determination" subject to administrative and judicial review under part 498 of this chapter.

6. In § 410.105, the introductory text and paragraph (b) are revised to read as follows:

§ 410.105 Requirements for coverage of CORF services.

Services specified in § 410.100 and not excluded under § 410.102 are covered as CORF services if they are furnished by a participating CORF (that is, a CORF that meets the conditions of subpart B of part 485 of this chapter, and has in effect a provider agreement under part 489 of this chapter) and if the following requirements are met:

* * * * *

(b) *When and where services are furnished.* (1) All services must be furnished while the individual is under the care of a physician.

(2) Except as provided in paragraph (b)(3) of this section, the services must be furnished on the premises of the CORF.

(3) *Exceptions.* (i) Physical therapy, occupational therapy, and speech pathology services may be furnished away from the premises of the CORF.

(ii) The single home visit specified in § 410.100(m) is also covered.

* * * * *

7. In § 410.152, paragraph (a)(1) is republished, and paragraphs (a)(1)(iv), (a)(2)(iii), and (i) are revised to read as follows:

§ 410.152 Amounts of payment.

(a) *General provisions*—(1) *Exclusion from incurred expenses.* As used in this section, "incurred expenses" are expenses incurred by an individual, during his or her coverage period, for covered Part B services, excluding the following:

* * * * *

(iv) In the case of physician and CORF services for the treatment of a mental, psychoneurotic, or personality disorder, furnished to an individual who is not an inpatient of a hospital, the expenses excluded from incurred expenses under § 410.155(c).

* * * * *

(2) *Other applicable provisions.* * * *

* * * * *

(iii) The special rules for payment to health maintenance organizations (HMOs), health care prepayment plans (HCPPs), and competitive medical plans (CMPs) that are set forth in part 417 of this chapter. (A prepayment organization that does not qualify as an HMO, CMP, or HCPP is paid in accordance with paragraph (b)(4) of this section.)

* * * * *

(i) *Amount of payment: ASC facility services.* For ASC facility services that are furnished in connection with the surgical procedures specified in part 416 of this chapter, Medicare Part B pays 80 percent of a standard overhead amount, as specified in § 416.120(c) of this chapter.[1]

[1] For services furnished before July 1, 1987, Medicare Part B paid 100 percent of the standard amount.

8. In § 410.155, paragraph (b) is republished, and paragraph (c) is revised to read as follows:

§ 410.155 Psychiatric services limitations: Expenses incurred for physician services and CORF services.

* * * * *

(b) *Services subject to limitation.* The psychiatric services limitation applies to physician services and CORF services (furnished by physicians or nonphysicians) for the treatment of a mental, psychoneurotic, or personality disorder, when the services are furnished to an individual who is not an inpatient in a hospital.

(c) *Limitation on incurred expenses*—(1) *Current limit.* For purposes of §§ 410.152 and 410.160, incurred expenses for the services specified in paragraph (b) of this section exclude expenses that are in excess of 62½ percent of the sum of the reasonable charges for physician services and the customary charges for CORF services.

(2) *Previous limits.* For years before calendar year 1990, incurred expenses that could be considered were limited to the lower of the current 62½ percent and a fixed dollar amount that—

(i) For calendar years before 1988, was $312.50;

(ii) For calendar year 1988, was $562.50; and

(iii) For calendar year 1989, was $1,375.

* * * * *

9. In §410.160, paragraph (a) is republished, and paragraph (b) is revised to read as follows:

§ 410.160 Part B annual deductible.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, incurred expenses (as defined in § 410.152) are subject to, and count toward meeting the annual deductible.

(b) *Exceptions.*[8] The following incurred expenses are not subject to the Part B annual deductible and do not count toward meeting that deductible:

(1) Home health services.

(2) Pneumococcal vaccines and their administration.

* * * * *

E. Part 413 is amended as set forth below:

[8] The deductible provisions did not apply to ASC facility services that were furnished before July 1987, nor to physician services that were furnished before April 1988 and that met the requirements for payment of 100 percent of the reasonable charges.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT: PAYMENT FOR END-STAGE RENAL DISEASE SERVICES

1. The authority citation is revised to read as follows:

Authority: Secs. 1102, 1122, 1814(b), 1815, 1833 (a), and (n), 1861(v), 1871, 1881, and 1886 of the Social Security Act as amended (42 U.S.C. 1302, 1320a–1, 1395f(b), 1395g, 1395l (a) and (n), 1395x(v), 1395hh, 1395rr, and 1395ww).

2. Section 413.13 is amended to add new paragraphs (c)(3) and (c)(4), to read as follows:

§ 413.13 Amount of payments if customary charges for services furnished are less than reasonable costs.

* * * * *

(c) * * *

(3) *Hospital outpatient radiology services.* The reasonable costs and customary charges for hospital outpatient radiology services furnished on or after October 1, 1988, that are subject to the payment method described in § 413.122, are aggregated and treated separately from all other hospital costs and charges incurred during the cost reporting period.

(4) *Other diagnostic procedures performed by a hospital on an outpatient basis.* The reasonable costs and customary charges for other diagnostic procedures identified by HCFA, that are performed on an outpatient basis by a hospital on or after October 1, 1989, and that are subject to the payment method described in § 413.122, are aggregated and treated separately from all other hospital costs or charges incurred during the cost reporting period.

3. A new § 413.122 is added, to read as follows:

§ 413.122 Payment for hospital outpatient radiology services and other diagnostic procedures.

(a) *Basis and purpose.* (1) This section implements section 1833(n) of the Act and establishes the method for determining Medicare payments for radiology services and other diagnostic procedures performed by a hospital on an outpatient basis.

(2) For purposes of this section—

(i) Radiology services include diagnostic and therapeutic radiology, nuclear medicine, CAT scan procedures, magnetic resonance imaging, ultrasound and other imaging services; and

(ii) Other diagnostic procedures are those identified by HCFA, and do not include diagnostic radiology procedures or diagnostic laboratory tests.

(b) *Payment for hospital outpatient radiology services.* (1) The aggregate payment for hospital outpatient radiology services furnished on or after October 1, 1988 is equal to the lesser of the following:

(i) The hospital's reasonable cost or customary charges, as determined in accordance with § 413.13, reduced by the applicable Part B annual deductible and coinsurance amounts.

(ii) The blended payment amount described in paragraph (b)(2) of this section.

(2) The blended payment amount for hospital outpatient radiology services furnished on or after October 1, 1988, but before October 1, 1989, is equal to the sum of—

(i) 65 percent of the hospital-specific amount (the hospital's reasonable cost or customary charges, whichever is less, reduced by the applicable Part B annual deductible and coinsurance amounts); and

(ii) 35 percent of a prevailing charge or fee schedule amount that is calculated as 80 percent of the amount determined by subtracting the applicable Part B annual deductible from 62 percent of the prevailing charges (or for services furnished on or after January 1, 1989, the fee schedule amount established) for the same services when furnished by participating physicians in their offices in the same locality.

(3) For hospital outpatient radiology services furnished on or after October 1, 1989, the blended payment amount is equal to the sum of 50 percent of the hospital-specific amount and 50 percent of the fee schedule amount.

(c) *Payment for other diagnostic procedures.* (1) The aggregate payment for other diagnostic procedures performed by a hospital on an outpatient basis on or after October 1, 1989 is equal to the lesser of the following:

(i) The hospital's reasonable cost or customary charges, as determined in accordance with § 414.13, reduced by the applicable Part B annual deductible and coinsurance amounts.

(ii) The blended payment described in paragraph (c)(2) of this section.

(2) The blended payment amount for other diagnostic procedures furnished on or after October 1, 1989, but before October 1, 1990, is equal to the sum of—

(i) 65 percent of the hospital-specific amount (the hospital's reasonable cost or customary charges, whichever is less, reduced by the applicable Part B annual deductible and coinsurance amounts); and

(ii) 35 percent of a prevailing charge amount that is calculated as 80 percent

of the amount determined by subtracting the applicable Part B annual deductible from 42 percent of the prevailing charges for the same services furnished by participating physicians in their offices in the same locality.

(3) For other diagnostic procedures performed by a hospital on or after October 1, 1990, the blended payment is equal to 50 percent of the hospital-specific amount and 50 percent of the prevailing charge amount.

F. Part 416 is amended as set forth below:

1. The table of contents is revised to read as follows:

PART 416—AMBULATORY SURGICAL SERVICES

Authority: Secs. 1102, 1832(a)(2), 1833, 1863 and 1864 of the Social Security Act (42 U.S.C. 1302, 1395k(a)(2), 13951, 1395z and 1395aa).

2. In subpart A, §§ 416.1 and 416.2 are revised, and § 416.3 is removed, to read as follows:

§ 416.1 Basis and scope.

(a) *Statutory basis.* (1) Section 1832(a)(2)(F)(i) of the Act provides for Medicare Part B coverage of facility services furnished in connection with surgical procedures specified by the Secretary under section 1833(i)(1) of the Act.

(2) Section 1833(i)(1)(A) of the Act requires the Secretary to specify the surgical procedures that can be performed safely on and ambulatory basis in an ambulatory surgical center, or a hospital outpatient department.

(3) Section 1833(i) (2)(A) and (3) specify the amounts to be paid for facility services furnished in connection with the specified surgical procedures when they are performed, respectively, in an ASC, or in a hospital outpatient department.

(b) *Scope.* This part sets forth—

(1) The conditions that an ASC must meet in order to participate in the Medicare program;

(2) The scope of covered services; and

(3) The conditions for Medicare payment for facility services.

§ 416.2 Definitions.

As used in this part:

Ambulatory surgical center or *ASC* means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, has an agreement with HCFA under Medicare to participate as an ASC, and meets the conditions set forth in subparts B and C of this part.

ASC services means facility services that are furnished in an ASC.

Covered surgical procedures means those surgical and other medical procedures that meet the criteria specified in § 416.65 and are published by HCFA in the **Federal Register**.

Facility services means services that are furnished in connection with covered surgical procedures performed in an ASC, or in a hospital on an outpatient basis.

3. In subpart B, the subpart heading and § 416.25 are revised, a new § 416.26 is added, § 416.30 is amended by revising the introductory text and paragraphs (a), (b), (e), and (f) to read as follows, and the undesignated center heading entitled "Conditions of Coverage" and §§ 416.20 and 416.39 are removed.

Subpart B—General Conditions and Requirements

§ 416.25 Basic requirements.

Participation as an ASC is limited to facilities that—

(a) Meet the definition in § 416.2; and

(b) Have in effect an agreement obtained in accordance with this subpart.

§ 416.26 Qualifying for an agreement.

(a) *Deemed compliance.* HCFA may deem an ASC to be in compliance with any or all of the conditions set forth in subpart C of this part if—

(1) The ASC is accredited by a national accrediting body, or licensed by a State agency, that HCFA determines provides reasonable assurance that the conditions are met;

(2) In the case of deemed status through accreditation by a national accrediting body, where State law requires licensure, the ASC complies with State licensure requirements; and

(3) The ASC authorizes the release to HCFA, of the findings of the accreditation survey.

(b) *Survey of ASCs.* (1) Unless HCFA deems the ASC to be in compliance with the conditions set forth in subpart C of this part, the State survey agency must survey the facility to ascertain compliance with those conditions, and report its findings to HCFA.

(2) HCFA surveys deemed ASCs on a sample basis as part of HCFA's validation process.

(c) *Acceptance of the ASC as qualified to furnish ambulatory surgical services.* If HCFA determines, after reviewing the survey agency recommendation and other evidence relating to the qualification of the ASC, that the facility meets the requirements of this part, it sends to the ASC—

(1) Written notice of the determination; and

(2) Two copies of the ASC agreement.

(d) *Filing of agreement by the ASC.* If the ASC wishes to participate in the program, it must—

(1) Have both copies of the ASC agreement signed by its authorized representative; and

(2) File them with HCFA.

(e) *Acceptance by HCFA.* If HCFA accepts the agreement filed by the ASC, returns to the ASC one copy of the agreement, with a notice of acceptance specifying the effective date.

(f) *Appeal rights.* If HCFA refuses to enter into an agreement or if HCFA terminates an agreement, the ASC is entitled to a hearing in accordance with Part 498 of this chapter.

§ 416.30 Terms of agreement with HCFA.

As part of the agreement under § 416.26 the ASC must agree to the following:

(a) *Compliance with coverage conditions.* The ASC agrees to meet the conditions for coverage specified in subpart C of this part and to report promptly to HCFA any failure to do so.

(b) *Limitation on charges to beneficiaries.*[1] The ASC agrees to charge the beneficiary or any other person only the applicable deductible and coinsurance amounts for facility services for which the beneficiary—

(1) Is entitled to have payment made on his or her behalf under this part; or

(2) Would have been so entitled if the ASC had filed a request for payment in accordance with § 410.165 of this chapter.

* * * * *

(e) *Acceptance of assignment.* The ASC agrees to accept assignment for all facility services furnished in connection with covered surgical procedures. For purposes of this section, assignment means an assignment under § 424.55 of this chapter of the right to receive payment under Medicare Part B and payment under § 424.64 of this chapter (when an individual dies before assigning the claim).

(f) *ASCs operated by a hopsital.* In an ASC operated by a hospital—

(1) The agreement is made effective on the first day of the next Medicare cost reporting period of the hospital that operates the ASC; and

(2) The ASC participates and is paid only as an ASC, without the option of converting to or being paid as a hospital outpatient department, unless HCFA determines there is good cause to do otherwise.

(3) Costs for the ASC are treated as a non-reimbursable cost center on the hopsital's cost report.

* * * * *

§ 416.35 [Amended]

3a. In § 416.35, the following changes are made:

a. In paragraph (b)(2), "will send" is changed to "sends".

b. In paragraph (c) "will not be" is changed to "is not".

§ 416.39 [Removed]

4. Section 416.39 is removed.

[1] For facility services furnished before July 1987, the ASC had to agree to make no charge to the beneficiary, since those services were not subject to the part B deductible and coinsurance provisions.

Subpart C—[Redesignated as Subpart E]

4a. Subpart C is redesignated as subpart E.

Subpart C—[Added]

5. Sections 416.40 through 416.49 are designated under a new "Subpart C—Specific Conditions for Coverage".

6. The undesignated center heading entitled "Scope of Benefits" is designated to read: "Subpart D—Scope of Benefits."

Subpart D—Scope of Benefits

7. In newly designated subpart D, §§ 416.60 and 416.61 are revised to read as follows:

§ 416.60 General rules.

(a) The services payable under this part are facility services furnished to Medicare beneficiaries, by a participating facility, in connection with covered surgical procedures specified in § 416.65.

(b) The surgical procedures, including all preoperative and post-operative services that are performed by a physician, are covered as physician services under part 410 of this chapter.

§ 416.61 Scope of facility services.

(a) *Included services.* Facility services include, but are not limited to—

(1) Nursing, technician, and related services;

(2) Use of the facilities where the surgical procedures are performed;

(3) Drugs, biologicals, surgical dressings, supplies, splints, casts, and appliances and equipment directly related to the provision of surgical procedures;

(4) Diagnostic or therapeutic services or items directly related to the provision of a surgical procedure;

(5) Administrative, recordkeeping and housekeeping items and services; and

(6) Materials for anesthesia.

(7) Intra-ocular lenses (IOLs).

(b) Excluded services.

Facility services do not include items and services for which payment may be made under other provisions of Part 405 of this chapter, such as physicians' services, laboratory, X-ray or diagnostic procedures (other than those directly related to performance of the surgical procedure), prosthetic devices (except IOLs), ambulance services, leg, arm, back and neck braces, artificial limbs, and durable medical equipment for use in the patient's home.

8. Redesignated subpart E is amended to revise the subpart heading, remove §§ 416.100 and 416.110, and revise §§ 416.120 and 416.125 to read as follows:

Subpart E—Payment for Facility Services

§ 416.120 Basis for payment.

The basis for payment depends on where the services are furnished.

(a) *Hospital outpatient department.* Payment will be in accordance with part 413 of this chapter.

(b) [Reserved]

(c) *ASC*—(1) *General rule.* Payment is based on a prospectively determined rate. This rate covers the cost of services such as supplies, nursing services, equipment, etc., as specified in § 416.61. The rate does not cover physician services or other medical services covered under part 410 of this chapter (for example, X-ray services or laboratory services) which are not directly related to the performance of the surgical procedures. Those services may be billed separately and paid on a reasonable charge basis.

(2) *Single and multiple surgical procedures.* (i) If one covered surgical procedure is furnished to a beneficiary in an operative session, payment is based on the prospectively determined rate for that procedure.

(ii) If more than one surgical procedure is furnished in a single operative session, payment is based on—

(A) The full rate for the procedure with the highest prospectively determined rate; and

(B) One half of the prospectively determined rate for each of the other procedures.

(3) *Deductibles and coinsurance.* Part B deductible and coinsurance amounts apply as specified in § 410.152 (a) and (i) of this chapter.

§ 416.125 ASC facility services payment rate.

(a) The payment rate is based on a prospectively determined standard overhead amount per procedure derived from an estimate of the costs incurred by ambulatory surgical centers generally in providing services furnished in connection with the performance of that procedure.

(b) The payment must be substantially less than would have been paid under the program if the procedure had been performed on an inpatient basis in a hospital.

§ 416.130 [Amended]

8a. In § 416.130, "will publish", wherever it appears, is changed to "publishes", and "will also explain" is changed to "also explains".

8b. In § 416.140, the section heading and paragraph (a) are revised, and a

heading is provided for paragraph (b), to read as follows:

§ 416.140 Surveys.

(a) *Timing, purpose, and procedures.* (1) No more often than once a year, HCFA conducts a survey of a randomly selected sample of participating ASCs to collect data for analysis or reevaluation of payment rates.

(2) HCFA notifies the selected ASCs by mail of their selection and of the form and content of the report the ASCs are required to submit within 60 days of the notice.

(3) If the facility does not submit an adequate report in response to HCFA's survey request, HCFA may terminate the agreement to participate in the Medicare program as an ASC.

(4) HCFA may grant a 30-day postponement of the due date for the survey report if it determines that the facility has demonstrated good cause for the delay.

(b) *Requirements for ASCs.* * * *

* * * * *

G. Part 424.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

1. The authority citation continues to read as follows:

Authority: Secs. 216(j), 1102, 1814, 1815(c), 1835, 1842(b), 1861, 1866(d), 1870 (e) and (f), 1871, and 1872 of the Social Security Act (42 U.S.C. 416(j), 1302, 1395f, 1395g(c), 1395n, 1395u(b), 1395x, 1395cc(d), 1395gg (e) and (f), 1395hh, and 1395ii).

2. In § 424.11, the introductory text of paragraph (e) is republished and paragraph (e)(3) is revised to read as follows:

§ 424.11 General procedures.

* * * * *

(e) *Limitation on authorization to sign statements.* A physician certification or recertification statement may be signed only by one of the following:

* * * * *

(3) A doctor of podiatric medicine if his or her certification is consistent with the functions he or she is authorized to perform under State law.

3. Section 424.22 is amended to revise paragraphs (a)(1)(iii) and (a)(1)(iv) and to remove and reserve paragraph (c), to read as follows:

§ 424.22 Requirements for home health services.

(a) *Certification*—

(1) Content of certification. * * *

* * * * *

(iii) A plan for furnishing the services has been established and is periodically reviewed by a physician who is a doctor of medicine, osteopathy, or podiatric medicine, and who is not precluded from performing this function under paragraph (d) of this section. (A doctor of podiatric medicine may perform only plan of treatment functions that are consistent with the functions he or she is authorized to perform under State law.)

(iv) The services were furnished while the individual was under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.[1]

* * * * *

4. Section 424.24 is amended to revise paragraphs (a), (b), and (c)(1), redesignate paragraph (e) as (f), and add a new paragraph (e), to read as follows:

§ 424.24 Requirements for medical and other health services under Medicare Part B.

(a) *Exempted services.* Certification is not required for the following: (1) Hospital services and supplies incident to physicians' services furnished to outpatients. The exemption applies to drugs and biologicals that cannot be self-administered, but not to partial hospitalization services, as set forth in paragraph (e) of this section.

(2) Outpatient hospital diagnostic services, including necessary drugs and biologicals, ordinarily furnished or arranged for by a hospital for the purpose of diagnostic study.

(3) Outpatient physical therapy services furnished in the patient's home or in the practitioner's office, by or under the direct supervision of a qualified physical therapist in independent practice. (See § 424.25 for plan of treatment requirements applicable to these services.)

(b) *General rule.* Medicare Part B pays for medical and other health services not exempted under paragraph (a) of this section only if a physician certifies the content specified in paragraph (c)(1), (c)(4), (d), (e) or (f)(1) of this section, as appropriate.

(c) *Outpatient physical therapy and speech pathology services*—(1) *Content of certification.* (i) The individual needs, or needed, physical therapy or speech pathology services.

(ii) The services were furnished while the individual was under the care of a physician. (For physical therapy services furnished after July 17, 1984, the physician may be a doctor of podiatric medicine, provided the services are consistent with the functions he or she is authorized to perform under State law.)

(iii) The services were furnished under a plan of treatment that meets the requirements of § 424.25.

* * * * *

(e) *Partial hospitalization services: Content of certification and plan of treatment requirements*—(1) *Content of certification.* (i) The individual would require inpatient psychiatric care if the partial hospitalization services were not provided.

(ii) The services are or were furnished while the individual was under the care of a physician.

(iii) The services were furnished under a written plan of treatment that meets the requirements of paragraph (e)(2) of this section.

(2) *Plan of treatment requirements.* (i) The plan is an individualized plan that is established and is periodically reviewed by a physician in consultation with appropriate staff participating in the program, and that sets forth—

(A) The physician's diagnosis;

(B) The type, amount, duration, and frequency of the services; and

(C) The treatment goals under the plan.

(ii) The physician determines the frequency and duration of the services taking into account accepted norms of medical practice and a reasonable expectation of improvement in the patient's condition.

H PART 430—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

1. The authority citation continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

§ 430.2 [Amended]

2. In paragraph (b), the listing of part 16 is changed to read:

Part 16—Procedures of the Departmental Appeals Board.

§ 430.3 [Amended]

3. In paragraph (b), "Departmental Grants Appeals Board" is changed to "Departmental Appeals Board".

§ 430.20 [Amended]

4. a. In paragraph (b)(1), the following is inserted immediately before "or": "increases the payment amounts for services already included in the plan,".

b. Paragraph (b)(2) is redesignated as paragraph (b)(3).

c. A new paragraph (b)(2) is added to read as follows:

(b) * * *

(2) For a plan amendment that changes the State's payment method

[1] As a condition of Medicare Part A payment for home health services furnished before July 1981, the physician was also required to certify that the services were needed for a condition for which the individual had received inpatient hospital or SNF services.

and standards, the rules of § 447.256 of this chapter apply.

5. A new § 430.25 is added to read as follows:

§ 430.25 Waivers of State plan requirements.

(a) *Scope of section.* This section describes the purpose and effect of waivers, identifies the requirements that may be waived and the other regulations that apply to waivers, and sets forth the procedures that HCFA follows in reviewing and taking action on waiver requests.

(b) *Purpose of waivers.* Waivers are intended to provide the flexibility needed to enable States to try new or different approaches to the efficient and cost-effective delivery of health care services, or to adapt their programs to the special needs of particular areas or groups of recipients. Waivers allow exceptions to State plan requirements and permit a State to implement innovative programs or activities on a time-limited basis, and subject to specific safeguards for the protection of recipients and the program. Detailed rules for waivers are set forth in subpart B of part 431, subpart A of part 440, and subpart G of part 441 of this chapter.

(c) *Effect of waivers.* (1) Waivers under section 1915(b) allow a State to take the following actions:

(i) Implement a primary care case-management system or a specialty physician system.

(ii) Designate a locality to act as central broker in assisting Medicaid recipients to choose among competing health care plans.

(iii) Share with recipients (through provision of additional services) cost-savings made possible through the recipients' use of more cost-effective medical care.

(iv) Limit recipients' choice of providers (except in emergency situations and with respect to family planning services) to providers that fully meet reimbursement, quality, and utilization standards, which are established under the State plan and are consistent with access, quality, and efficient and economical furnishing of care.

(2) A waiver under section 1915(c) of the Act allows a State to include as "medical assistance" under its plan home and community based services furnished to recipients who would otherwise need inpatient care that is furnished in a hospital, SNF, ICF, or ICF/MR, and is reimbursable under the State plan.

(3) A waiver under section 1916 (a)(3) or (b)(3) of the Act allows a State to impose a deduction, cost-sharing or similar charge of up to twice the "nominal charge" established under the plan for outpatient services, if—

(i) The outpatient services are received in a hospital emergency room but are not emergency services; and

(ii) The State has shown that Medicaid recipients have actually available and accessible to them alternative services of nonemergency outpatient services.

(d) *Requirements that are waived.* In order to permit the activities described in paragraph (c) of this section, one or more of the title XIX requirements must be waived, in whole or in part.

(1) Under section 1915(b) of the Act, and subject to certain limitations, any of the State plan requirements of section 1902 of the Act may be waived to achieve one of the purposes specified in that section.

(2) Under section 1915(c) of the Act, the following requirements may be waived:

(i) Statewideness—section 1902(a)(1).

(ii) Comparability of services—section 1902(a)(10)(B).

(iii) Income and resource rules—section 1902(a)(10)(C)(i)(III).

(3) Under section 1916 of the Act, paragraphs (a)(3) and (b)(3) require that any cost-sharing imposed on recipients be nominal in amount, and provide an exception for nonemergency services furnished in a hospital emergency room if the conditions of paragraph (c)(3) of this section are met.

(e) *Submittal of waiver request.* (1) The State Governor, the head of the Medicaid agency, or an authorized designee may submit the waiver request.

(f) *Review of waiver requests.* (1) This paragraph applies to initial waiver requests and to requests for renewal or amendment of a previously approved waiver.

(2) HCFA regional and central office staff review waiver requests and submit a recommendation to the Administrator, who—

(i) Has the authority to approve or deny waiver requests; and

(ii) Does not deny a request without first consulting the Secretary.

(3) A waiver request is considered approved unless, within 90 days after the request is received by HCFA, the Administrator denies the request, or the Administrator or the Regional Administrator sends the State a written request for additional information necessary to reach a final decision. If additional information is requested, a new 90-day period begins on the day the response to the additional information request is received by the addressee.

(g) *Basis for approval*—(1) *Waivers under section 1915 (b) and (c).* The Administrator approves waiver requests if the State's proposed program or activity meets the requirements of the Act and the regulations at § 431.55 or subpart G of part 441 of this chapter.

(2) *Waivers under section 1916.* The Administrator approves a waiver under section 1916 of the Act if the State shows, to HCFA's satisfaction, that the Medicaid recipients have available and accessible to them sources, other than a hospital emergency room, where they can obtain necessary nonemergency outpatient services.

(h) *Effective date and duration of waivers*—(1) *Effective date.* Waivers receive a prospective effective date determined, with State input, by the Administrator. The effective date is specified in the letter of approval to the State.

(2) *Duration of waivers*—(i) *Home and community-based services under section 1915(c).* The initial waiver is for a period of three years and may be renewed thereafter for periods of five years.

(ii) *Waivers under sections 1915(b) and 1916.* The initial waiver is for a period of two years and may be renewed for additional periods of up to two years as determined by the Administrator.

(3) *Renewal of waivers.* (i) A renewal request must be submitted at least 90 days (but not more than 120 days) before a currently approved waiver expires, to provide adequate time for HCFA review.

(ii) If a renewal request for a section 1915(c) waiver proposes a change in services provided, eligible population, service area, or statutory sections waived, the Administrator may consider it a new waiver, and approve it for a period of three years.

§ 430.33 [Amended]

6. In paragraph (c)(2), the word "Grant" is removed.

§ 430.42 [Amended]

7.a. In paragraph (b)(1), the word "Grant" is removed.

b. In the introductory text of paragraph (b)(2), "Chairperson" is changed to "Chair", and the word "Grants" is removed.

I. Part 431

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

1. The authority citation continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. Subpart B is revised to read as follows:

Subpart B—General Administrative Requirement

Subpart B—General Administrative Requirements

§ 431.40 Basis and scope.

(a) This subpart sets forth State plan requirements and exceptions that pertain to the following administrative requirements and provisions of the Act:

(1) Statewideness—section 1902(a)(1);

(2) Proper and efficient administration—section 1902(a)(4);

(3) Comparability of services—section 1902(a)(10) (B)–(E);

(4) Payment for services furnished outside the State—section 1902(a)(16);

(5) Free choice of providers—section 1902(a)(23);

(6) Special waiver provisions applicable to American Samoa and the Northern Mariana Islands—section 1902(j); and

(7) Exceptions to, and waiver of, State plan requirements—sections 1915 (a)–(c) and 1916 (a)(3) and (b)(3).

(b) Other applicable regulations include the following:

(1) Section 430.25 Waivers of State plan requirements.

(2) Section 440.250 Limits on comparability of services.

§ 431.50 Statewide operation.

(a) *Statutory basis.* Section 1902(a)(1) of the Act requires a State plan to be in effect throughout the State, and section 1915 permits certain exceptions.

(b) *State plan requirements.* A State plan must provide that the following requirements must be met:

(1) The plan will be in operation statewide through a system of local offices, under equitable standards for assistance and administration that are mandatory throughout the State.

(2) If administered by political subdivisions of the State, the plan will be mandatory on those subdivisions.

(3) The agency will ensure that the plan is continuously in operation in all local offices or agencies through—

(i) Methods for informing staff of State policies, standards, procedures, and instructions;

(ii) Systematic planned examination and evaluation of operations in local offices by regularly assigned State staff who make regular visits; and

(iii) Reports, controls, or other methods.

(c) *Exceptions.* (1) "Statewide operation" does not mean, for example, that every source of service must furnish the service State-wide. The requirement does not preclude the agency from contracting with a comprehensive health care organization (such as an HMO or a rural health clinic) that serves a specific area of the State, to furnish services to Medicaid recipients who live in that area and chose to receive services from that HMO or rural health clinic. Recipients who live in other parts of the State may receive their services from other sources.

(2) Other allowable exceptions and waivers are set forth in §§ 431.54 and 431.55.

§ 431.51 Free choice of providers.

(a) *Statutory basis.* This section is based on sections 1902(a)(23), 1902(e)(2), and 1915 (a) and (b) of the Act.

(1) Section 1902(a)(23) of the Act provides that recipients may obtain services from any qualified Medicaid provider that undertakes to provide the services to them.

(2) Section 1915(a) of the Act provides that a State shall not be found out of compliance with section 1902(a)(23) solely because it imposes certain specified allowable restrictions on freedom of choice.

(3) Section 1915(b) of the Act authorizes waiver of the section 1902(a)(23) freedom of choice of providers requirement in certain specified circumstances, but not with respect to providers of family planning services.

(4) Section 1902(a)(23), as amended by section 4113(c) of OBRA '87, provides that, for services furnished after June 1988, a recipient enrolled in a primary care case-management system, an HMO, or a similar entity, may not be denied freedom of choice of qualified providers of family planning services.

(5) Section 1902(e)(2), as amended by section 4113(c)(2) of OBRA '87, provides that HMO enrollees deemed eligible only for services furnished by the HMO (while they complete a minimum enrollment period) may, as an exception, seek family planning services from any qualified provider.

(b) *State plan requirements.* A State plan, except the plan for Puerto Rico, the Virgin Islands, or Guam, must provide as follows:

(1) Except as provided under paragraph (c) of this section, a recipient may obtain Medicaid services from any institution, agency, pharmacy, person, or organization that is—

(i) Qualified to furnish the services; and

(ii) Willing to furnish them to that particular recipient.

This includes an organization that furnishes, or arranges for the furnishing of, Medicaid services on a prepayment basis.

(2) A recipient enrolled in a primary care case-management system, an HMO, or other similar entity will not be restricted in freedom of choice of providers of family planning services.

(c) *Exceptions.* Paragraph (b) of this section does not prohibit the agency from—

(1) Establishing the fees it will pay providers for Medicaid services;

(2) Setting reasonable standards relating to the qualifications of providers: or

(3) Subject to paragraph (b)(2) of this section, restricting recipients' free choice of providers in accordance with one or more of the exceptions set forth in § 431.54, or under a waiver as provided in § 431.55.

(d) *Certification requirement.* (1) *Content of certification.* If a State implements a project under one of the exceptions allowed under § 431.54 (d), (e) or (f), it must certify to HCFA that the statutory safeguards and requirements for an exception under section 1915(a) of the Act are met.

(2) *Timing of certification.* (i) For an exception under § 431.54(d), the State may not institute the project until after it has submitted the certification and HCFA has made the findings required under the Act, and so notified the State.

(ii) For exceptions under § 431.54 (e) or (f), the State must submit the certificate by the end of the quarter in which it implements the project.

§ 431.52 Payments for services furnished out of State.

(a) *Statutory basis.* Section 1902(a)(16) of the Act authorizes the Secretary to prescribe State plan requirements for furnishing Medicaid to State residents who are absent from the State.

(b) *Payment for services.* A State plan must provide that the State will pay for services furnished in another State to the same extent that it would pay for services furnished within its boundaries if the services are furnished to a recipient who is a resident of the State, and any of the following conditions is met:

(1) Medical services are needed because of a medical emergency;

(2) Medical services are needed and the recipient's health would be endangered if he were required to travel to his State of residence;

(3) The State determines, on the basis of medical advice, that the needed medical services, or necessary supplementary resources, are more readily available in the other State;

(4) It is general practice for recipients in a particular locality to use medical resources in another State.

(c) *Cooperation among States.* The plan must provide that the State will establish procedures to facilitate the furnishing of medical services to individuals who are present in the State and are eligible for Medicaid under another State's plan.

§ 431.53 Assurance of transportation.

A State plan must—

(a) Specify that the Medicaid agency will ensure necessary transportation for recipients to and from providers; and

(b) Describe the methods that the agency will use to meet this requirement.

(Sec. 1902(a)(4) of the Act)

§ 431.54 Exceptions to certain State plan requirements.

(a) *Statutory basis.* Section 1915(a) of the Act provides that a State shall not be deemed to be out of compliance with the requirements of sections 1902(a) (1), (10), or (23) of the Act solely because it has elected any of the exceptions set forth in paragraphs (b) and (d) through (f) of this section.

(b) *Additional services under a prepayment system.* If the Medicaid agency contracts on a prepayment basis with an organization that provides services additional to those offered under the State plan, the agency may restrict the provision of the additional services to recipients who live in the area served by the organization and wish to obtain services from it.

(c) [Reserved]

(d) *Special procedures for purchase of medical devices and laboratory and X-ray tests.* The Medicaid agency may establish special procedures for the purchase of medical devices or laboratory and X-ray tests (as defined in § 440.30 of this chapter) through a competitive bidding process or otherwise, if the State assures, in the certification required under § 431.51(d), and HCFA finds, as follows:

(1) Adequate services or devices are available to recipients under the special procedures.

(2) Laboratory services are furnished through laboratories that meet the following requirements:

(i) They are independent laboratories, or inpatient or outpatient hospital laboratories that provide services for individuals who are not hospital patients, or physician laboratories that process at least 100 specimens for other physicians during any calendar year.

(ii) They meet the requirements of subpart M of part 405 or part 482 of this chapter.

(iii) Laboratories that require an interstate license under 42 CFR part 74 are licensed by HCFA or receive an exemption from the licensing requirement by the College of American Pathologists. (Hospital and physician laboratories may participate in competitive bidding only with regard to services to non-hospital patients and other physicians' patients, respectively.)

(3) Any laboratory from which a State purchases services under this section has no more than 75 percent of its charges based on services to Medicare beneficiaries and Medicaid recipients.

(e) *Lock-in of recipients who over-utilize Medicaid services.* If a Medicaid agency finds that a recipient has utilized Medicaid services at a frequency or amount that is not medically necessary, as determined in accordance with utilization guidelines established by the State, the agency may restrict that recipient for a reasonable period of time to obtain Medicaid services from designated providers only. The agency may impose these restrictions only if the following conditions are met:

(1) The agency gives the recipient notice and opportunity for a hearing (in accordance with procedures established by the agency) before imposing the restrictions.

(2) The agency ensures that the recipient has reasonable access (taking into account geographic location and reasonable travel time) to Medicaid services of adequate quality.

(3) The restrictions do not apply to emergency services furnished to the recipient.

(f) *Lock-out of providers.* If a Medicaid agency finds that a Medicaid provider has abused the Medicaid program, the agency may restrict the provider, through suspension or otherwise, from participating in the program for a reasonable period of time.

Before imposing any restriction, the agency must meet the following conditions:

(1) Give the provider notice and opportunity for a hearing, in accordance with procedures established by the agency.

(2) Find that in a significant number or proportion of cases, the provider has:

(i) Furnished Medicaid services at a frequency or amount not medically necessary, as determined in accordance with utilization guidelines established by the agency; or

(ii) Furnished Medicaid services of a quality that does not meet professionally recognized standards of health care.

(3) Notify HCFA and the general public of the restriction and its duration.

(4) Ensure that the restrictions do not result in denying recipients reasonable access (taking into account geographic location: and reasonable travel time) to Medicaid services of adequate quality, including emergency services.

§ 431.55 Waiver of other Medicaid requirements.

(a) *Statutory basis.* Section 1915(b) of the Act, authorizes the Secretary to waive the requirements of sections 1902 of the Act to the extent he or she finds proposed improvements or specified practices in the provision of services under Medicaid to be cost-effective, efficient, and consistent with the objectives of the Medicaid program. Sections 1915 (e), (f), and (h) of the Act prescribe how such waivers are to be approved, continued, monitored, and terminated. Sections 1916 (a)(3) and (b)(3) of the Act specify the circumstances under which the Secretary is authorized to waive the requirement that cost-sharing amounts be nominal.

(1) General requirements for submittal of waiver requests, and the procedures that HCFA follows for review and action on those requests are set forth in § 430.25 of this chapter.

(2) In applying for a waiver to implement an approvable project under paragraph (c), (d), (e), or (f) of this section, a Medicaid agency must document in the waiver request and maintain data regarding:

(i) The cost-effectiveness of the project;

(ii) The effect of the project on the accessibility and quality of services; and

(iii) The anticipated impact of the project on the State's Medicaid program.

(3) No waiver under this section may be granted for a period longer than 2 years, unless the agency requests a continuation of the waiver.

(4) HCFA monitors the implementation of waivers granted under this section to ensure that requirements for such waivers are being met.

(i) If monitoring demonstrates that the agency is not in compliance with the requirements for a waiver under this section, HCFA gives the agency notice and opportunity for a hearing.

(ii) If, after a hearing, HCFA finds an agency to be out of compliance with the requirements of a waiver, HCFA terminates the waiver and gives the agency a specified date by which it must demonstrate that it meets the applicable requirements of section 1902 of the Act.

(c) *Case-management system.* (1) Waivers of appropriate requirements of section 1902 of the Act may be authorized for a State to implement a primary care case-management system or specialty physician services system.

(i) Under a primary care case-management system the agency assures that a specific person or persons or agency will be responsible for locating, coordinating, and monitoring all primary care or primary care and other medical care and rehabilitative services on behalf of a recipient.

(ii) A specialty physician services system allows States to restrict recipients of specialty services to designated providers of such services, even in the absence of a primary care case-management system.

(2) A waiver under this paragraph (c) may not be approved unless the State's request assures that the restrictions—

(i) Do not apply in emergency situations; and

(ii) Do not substantially impair access to medically necessary services of adequate quality.

(d) *Locality as central broker.* Waivers of appropriate requirements of section 1902 of the Act may be authorized for a State to allow a locality to act as a central broker to assist recipients in selecting among competing health care plans. States must ensure that access to medically necessary services of adequate quality is not substantially impaired.

(1) A locality is any defined jurisdiction, e.g., district, town, city, borough, county, parish, or State.

(2) A locality may use any agency or agent, public or private, profit or nonprofit, to act on its behalf in carrying out its central broker function.

(e) *Sharing of cost savings.* (1) Waivers of appropriate requirements of section 1902 of the Act may be authorized for a State to share with recipients the cost savings resulting from the recipients' use of more cost-effective medical care.

(2) Sharing is through the provision of additional services, including—

(i) Services furnished by a plan selected by the recipient; and

(ii) Services expressly offered by the State as an inducement for recipients to participate in a primary care case-management system, a competing health care plan or other system that furnishes health care services in a more cost-effective manner.

(f) *Restriction of freedom of choice*—(1) Waiver of appropriate requirements of section 1902 of the Act may be authorized for States to restrict recipients to obtaining services from (or through) qualified providers or practitioners that meet, accept, and comply with the State reimbursement, quality and utilization standards specified in the State's waiver request.

(2) An agency may qualify for a waiver under this paragraph (f) only if its applicable State standards are consistent with access, quality and efficient and economic provision of covered care and services and the restrictions it imposes—

(i) Do not apply to recipients residing at a long-term care facility when a restriction is imposed unless the State arranges for reasonable and adequate recipient transfer.

(ii) Do not discriminate among classes of providers on grounds unrelated to their demonstrated effectiveness and efficiency in providing those services; and

(iii) Do not apply in emergency circumstances.

(3) Demonstrated effectiveness and efficiency refers to reducing costs or slowing the rate of cost increase and maximizing outputs or outcomes per unit of cost.

(g) *Cost sharing requirement.* (1) Under sections 1916 (a)(3) and (b)(3) of the Act, for nonemergency services furnished in a hospital emergency room, the Secretary may by waiver permit a State to impose a copayment of up to double the "nominal" copayment amounts determined under § 447.54(a)(3) of this chapter.

(2) Nonemergency services are services that do not meet the definition of emergency services at § 447.53(b)(4) of this chapter.

(3) In order for a waiver to be approved under this paragraph (g), the State must establish to the satisfaction of HCFA, that alternative sources of nonemergency, outpatient services are available and accessible to recipients.

(4) Although, in accordance with paragraph (b)(3) of this section, a waiver will generally be granted for a 2 year duration, HCFA will re-evaluate waivers approved under this paragraph (g) if the State increases the nominal copayment amounts in effect when the waiver was approved.

(5) A waiver approved under this paragraph cannot apply to services furnished before the waiver was granted.

§ 431.56 Special waiver provisions applicable to American Samoa and the Northern Mariana Islands.

(a) *Statutory basis.* Section 1902(j) of the Act provides for waiver of all but three of the title XIX requirements, in the case of American Samoa and the Northern Mariana Islands.

(b) *Waiver provisions.* American Samoa or the Northern Mariana Islands may request, and HCFA may approve, a waiver of any of the title XIX requirements except the following:

(1) The Federal medical assistance percentage specified in section 1903 of the Act and § 433.10(b) of this chapter.

(2) The limit imposed by section 1108(c) of the Act on the amount of Federal funds payable to American Samoa or the Northern Mariana Islands for care and services that meet the section 1905(a) definition for Medicaid assistance.

(3) The requirement that payment be made only with respect to expenditure made by American Samoa or the Northern Mariana Islands for care and services that meet the section 1905(a) definition of medical assistance.

J. Part 435.

PART 435—ELIGIBILITY IN THE STATES, DISTRICT OF COLUMBIA, THE NORTHERN MARIANA ISLANDS, AND AMERICAN SAMOA

1. The authority citation continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. Section 435.212 is revised to read as follows:

§ 435.212 Individuals who would be ineligible if they were not enrolled in an HMO.

The agency may provide that a recipient who is enrolled in a federally qualified HMO (under a risk contract as specified in § 434.20(a)(1) of this chapter) and who becomes ineligible for Medicaid is considered to continue to be eligible—

(a) For a period specified by the agency, ending no later than 6 months from the date of enrollment; and

(b) Except for family planning services (which the recipient may obtain from any qualified provider) only for services furnished to him or her as an HMO enrollee.

3. Section 435.725 is amended to revise paragraphs (a), (c)(1) introductory text, (c)(1) (i) and (ii), (c)(4), (c)(5), and (d), to read as follows:

§ 435.725 Post-eligibility treatment of income and resources of institutionalized individuals: Application of patient income to the cost of care.

(a) *Basic rules.* (1) The agency must reduce its payment to an institution, for services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraphs (c) and (d) of this section, from the individual's total income.

(2) The individual's income must be determined in accordance with paragraph (e) of this section.

(3) Medical expenses must be determined in accordance with paragraph (f) of this section.

* * * * *

(c) *Required deductions.* * * *

(1) *Personal needs allowance.* A personal needs allowance that is reasonable in amount for clothing and other personal needs of the individual while in the institution. This protected personal needs allowance must be at least—

(i) $30 a month for an aged, blind, or disabled individual, including a child applying for Medicaid on the basis of blindness or disability;

(ii) $60 a month for an institutionalized couple if both spouses are aged, blind, or disabled and their income is considered available to each other in determining eligibility; and

* * * * *

(4) *Expenses not subject to third party payment.* Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—

(i) Medicare and other health insurance premiums, deductibles, or coinsurance charges; and

(ii) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

(5) *Continued SSI and SSP benefits.* The full amount of SSI and SSP benefits that the individual continues to receive under sections 1611(e)(1) (E) and (G) of the Act.

(d) *Optional deduction: Allowance for home maintenance.* For single individuals and couples, an amount (in addition to the personal needs allowance) for maintenance of the individual's or couple's home if—

(1) The amount is deducted for not more than a 6-month period; and

(2) A physician has certified that either of the individuals is likely to return to the home within that period.

* * * * *

4. Section 435.733 is amended to revise paragraphs (a), (c)(1) introductory text, (c)(1) (i) and (ii), (c)(4), (c)(5), and (d), to read as follows:

§ 435.733 Post-eligibility treatment of income and resources of institutionalized individuals: Application of patient income to cost of care.

(a) *Basic rules.* (1) The agency must reduce its payment to an institution, for services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraphs (c) and (d) of this section, from the individual's total income.

(2) The individual's income must be determined in accordance with paragraph (e) of this section.

(3) Medical expenses must be determined in accordance with paragraph (f) of this section.

* * * * *

(c) *Required deductions.* * * *

(1) *Personal needs allowance.* A personal needs allowance that is reasonable in amount for clothing and other personal needs of the individual while in the institution. This protected personal needs allowance must be at least—

(i) $30 a month for an aged, blind, or disabled individual, including a child applying for Medicaid on the basis of blindness or disability;

(ii) $60 a month for an institutionalized couple if both spouses are aged, blind, or disabled and their income is considered available to each other in determining eligibility; and

(4) *Expenses not subject to third party payment.* Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—

(i) Medicare and other health insurance permiums, deductibles, or coinsurance charges; and

(ii) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

(5) *Continued SSI and SSP benefits.* The full amount of SSI and SSP benefits that the individual continues to receive under sections 1611(e)(1) (E) and (G) of the Act.

(d) *Optional deduction: Allowance for home maintenance.* For single individuals and couples, an amount (in addition to the personal needs allowance) for maintenance of the individual's or couple's home if—

(1) The amount is deducted for not more than a 6-month period; and

(2) A physician has certified that either of the individuals is likely to return to the home within that period.

* * * * *

5. Section 435.832 is amended to revise paragraphs (a), (c)(1) introductory text, (c)(1) (i) and (ii) (c)(4), and (d), to read as follows:

§ 435.832 Post-eligibility treatment of income and resources of institutionalized individuals: Application of patient income to the cost of care.

(a) *Basic rules.* (1) The agency must reduce its payment to an institution, for services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraphs (c) and (d) of this section, from the individual's total income.

(2) The individual's income must be determined in accordance with paragraph (e) of this section.

(3) Medical expenses must be determined in accordance with paragraph (f) of this section.

* * * * *

(c) *Required deductions.* * * *

(1) *Personal needs allowance.* A personal needs allowance that is reasonable in amount for clothing and other personal needs of the individual while in the institution. This protected personal needs allowance must be at least—

(i) $30 a month for an aged, blind, or disabled individual, including a child applying for Medicaid on the basis of blindness or diability.

(ii) $60 a month for an institutionalized couple if both spouses are aged, blind, or disabled and their income is considered available to each other in determining eligibility; and

* * * * *

(4) Expenses not subject to third party payment. Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—

(i) Medicare and other health insurance permiums, deductibles, or coinsurance charges; and

(ii) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

(d) *Optional deduction: Allowance for home maintenance.* For single individuals and couples, an amount (in addition to the personal needs allowance) for maintenance of the individual's or couple's home if—

(1) The amount is deducted for not more than a 6-month period; and

(2) A physician has certified that either of the individuals is likely to return to the home within that period.

* * * * *

K. Part 436.

PART 436—ELIGIBILITY IN GUAM, PUERTO RICO AND THE VIRGIN ISLANDS

1. The authority citation continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. Section 436.832 is amended to revise paragraphs (a), (c)(1), (c)(4) and (d) to read as follows:

§ 436.832 Post-eligibility treatment of income and resources of institutionalized individuals: Application of patient income to cost of care.

(a) *Basic rules.* (1) The agency must reduce its payment to an institution, for services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraphs (c) and (d) of this section from the individual's total income.

(2) The individual's income must be determined in accordance with paragraph (e) of this section.

(3) Medical expenses must be determined in accordance with paragraph (f) of this section.

* * * * *

(c) *Required deductions.* * * *

(1) *Personal needs allowance.* A personal needs allowance that is reasonable in amount for clothing and other personal needs of the individual while in the institution. This protected personal needs allowance must be at least—

(i) $30 a month for an aged, blind, or disabled individual, including a child applying for Medicaid on the basis of blindness or disability;

(ii) $60 a month for an institutionalized couple if both spouses are aged, blind, or disabled and their income is considered available to each other in determining eligibility; and

(iii) For other individuals, a reasonable amount set by the agency, based on a reasonable difference in their personal needs from those of the aged, blind, or disabled.

* * * * *

(4) *Expenses not subject to third party payment.* Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—

(i) Medicare and other health insurance premiums, deductibles, or coinsurance charges; and

(ii) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

(d) *Optional deduction: Allowance for home maintenance.* For single individuals and couples, an amount (in addition to the personal needs allowance) for maintenance of the individual's or couple's home if—

(i) The amount is deducted for not more than a 6-month period; and

(ii) A physician has certified that either of the individuals is likely to return to the home within that period.

* * * * *

L. Part 440.

PART 440—SERVICES: GENERAL PROVISIONS

1. The authority citation continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. Section 440.50 is revised to read as follows:

§ 440.50 Physicians' services and medical and surgical services of a dentist.

(a) "Physicians' services," whether furnished in the office, the recipient's home, a hospital, a skilled nursing facility, or elsewhere, means services furnished by a physician—

(1) Within the scope of practice of medicine or osteopathy as defined by State law; and

(2) By or under the personal supervision of an individual licensed under State law to practice medicine or osteopathy.

(b) "Medical and surgical services of a dentist" means medical and surgical services furnished, on or after January 1, 1988, by a doctor of dental medicine or dental surgery if the services are services that—

(1) If furnished by a physician, would be considered physician's services.

(2) Under the law of the State where they are furnished, may be furnished either by a physician or by a doctor of dental medicine or dental surgery; and

(3) Are furnished by a doctor of dental medicine or dental surgery who is authorized to furnish those services in the State in which he or she furnished the services.

3. Section 440.90 is revised to read as follows:

§ 440.90 Clinic services.

Clinic services means preventive, diagnostic, therapeutic, rehabilitative, or palliative services that are furnished by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients. The term includes the following services furnished to outpatients:

(a) Services furnished at the clinic by or under the direction of a physician or dentist.

(b) Services furnished outside the clinic, by clinic personnel under the direction of a physician, to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address.

(c) Services furnished at the clinic that are nurse-midwife services, as defined in § 440.165.

M. Part 441.

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

1. The authority citation continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

§ 441.10 [Amended]

2. Paragraph (f) of § 441.10 is revised to read as follows:

(f) Section 1903(i)(1) for organ transplant procedures, and 1903(i)(5) for certain prescribed drugs.

3. A new § 441.35 is added, to read as follows:

§ 441.35 Organ transplants.

(a) FFP is available in expenditures for services furnished in connection with organ transplant procedures only if the State plan includes written standards for the coverage of those procedures, and those standards provide that—

(1) Similarly situated individuals are treated alike; and

(2) Any restriction on the practitioners or facilities that may provide organ transplant procedures is consistent with the accessibility of high quality care to individuals eligible for the procedures under the plan.

(b) Nothing in paragraph (a) permits a State to provide, under its plan, services that are not reasonable in amount, duration, and scope to achieve their purpose.

N. Part 482.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

1. The authority citation continues to read as follows:

Authority: Secs. 1102, 1138, 1814(a)(6), 1861 (e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act (42 U.S.C. 1302, 1338, 1395f(a)(6), 1395x (e), (f), (k), (r), (v)(1)(G), (z),

and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396a(a)(30), and 1396(a)).

2. In § 482.12, the introductory text of paragraph (c) is republished and paragraphs (c)(1) introductory text, (c)(2) and (c)(4) are revised to read as follows:

§ 482.12 Condition of participation: Governing body.

* * * * *

(c) *Standard: Care of patients.* In accordance with hospital policy, the governing body must ensure that the following requirements are met:

(1) Every Medicare patient is under the care of:

* * * * *

(2) Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital. If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) of this section, that patient is under the care of a doctor of medicine or osteopathy.

* * * * *

(4) A doctor of medicine or osteopathy is responsible for the care of each Medicare patient with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization and that is not specifically within the scope of practice, as defined by the medical staff and permitted by State law and as limited by paragraphs (c)(1) (iv) and (v) of this section, of any of the practitioners specified in paragraphs (c)(1) (ii) through (v) of this section.

* * * * *

O. Part 485.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

1. The authority citation continues to read as follows:

Authority: Secs. 1102, 1861 (aa) and (cc), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x (aa) and (cc), and 1395(hh)).

2. The § 485.58, paragraph (e) is revised to read as follows:

§ 485.58 Condition of participation: Comprehensive rehabilitation program.

* * * * *

(e) *Standard: Scope and site of services*—(1) *Basic requirements.* The facility must provide all the CORF services required in the plan of treatment and, except as provided in paragraph (e)(2) of this section, must provide the services on its premises.

(2) *Exceptions.* Physical therapy, occupational therapy, and speech pathology services furnished away from the premises of the CORF may be covered as CORF services if Medicare payment is not otherwise made for these services. In addition, a single home visit is covered if there is need to evaluate the potential impact of the home environment on the rehabilitation goals.

P. Part 489

Q. Technical Amendments.

1. Nomenclature Changes. Throughout this chapter IV, all references to "section 1910(c) of the Act" are changed to "section 1910(b) of the Act".

PART 400—INTRODUCTION; DEFINITIONS

1. The authority citation for part 400 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. chapter 35.

§ 400.200 [Amended]

2. In § 400.200, the following statements are added in alphabetical order:

CMP stands for competitive medical plan.

Conditions of participation includes *requirements for participation* as the latter term is used in part 483 of this chapter.

Condition level deficiencies includes deficiencies with respect to "level A requirements" as the latter term is used in parts 442 and 483 of this chapter.

CORF stands for comprehensive outpatient rehabilitation facility.

HCPP stands for health care prepayment plan.

ICF/MR stands for intermediate care facility for the mentally retarded.

OIG stands for the Department's Office of the Inspector General.

§ 400.202 [Amended]

3. In § 400.202, in the definition of *Provider*, the phrase "effective November 1, 1983 through September 30, 1986," is removed.

§ 400.203 [Amended]

4. In § 400.203, the definition of *Services* is revised to read: *Services* means the types of medical assistance specified in section 1905(a) of the Act and defined in subpart A of part 440 of this chapter.

§ 408.24 [Amended]

5. In § 408.24, in paragraphs (a)(6)(ii) and (a)(7)(ii), "section 9319(c) of Pub. L. 99–509" is changed to "section 1837(i) of the Act".

§ 410.24 [Amended]

6. In § 410.24, the superscript for the footnote in the text and in the footnote is changed from "6" to "1".

§ 410.60 [Amended]

7. In § 410.60, the following changes are made:

(a) In paragraph (a)(2), "subpart B of part 424 of this chapter" is changed to "§ 410.63".

(b) In paragraph (c)(2), the superscript for the footnote in the text and in the footnote is changed from "7" to "2".

§ 410.62 [Amended]

8. In § 410.62, in paragraph (a)(2)(iii), "subpart B of part 424 of this chapter" is changed to "§ 410.63".

§ 410.160 [Amended]

9. In § 410.160, in paragraph (b)(1), the superscript for the footnote in the text and in the footnote is changed from "8" to "3".

§ 410.161 [Amended]

10. In § 410.161, the following changes are made:

a. In paragraph (a)(3), "Part A or" is inserted before "Part B", and the following sentence is added at the end: "The Part B blood deductible is reduced to the extent that a blood deductible has been applied under Part A.".

b. Paragraph (a)(6) is removed.

PART 417—HEALTH MAINTENANCE ORGANIZATIONS COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

1. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102, 1833(a)(1)(A), 1861(s)(2)(H), 1871, 1874, and 1876 of the Social Security Act (42 U.S.C. 1302, 1395l(a)(1)(A), 1395x(s)(2)(H), 1395hh, 1395kk, and 1395mm); sec. 114(c) of Pub. L. 97-248 (42 U.S.C. 1395mm note); 31 U.S.C. 9701; and secs. 215 and 1301 through 1318 of the Public Health Service Act (42 U.S.C. 216 and 300e through 300e-17), unless otherwise noted.

§ 417.104 [Amended]

2. In § 417.104, the footnote to paragraph (e) is revised as follows:

[1] Further information entitled "Guidelines for Rating by Class" may be obtained from the Office of Prepaid Health Care, Division of Qualification Analysis, HHS Cohen Bldg., Room 4360, 330 Independence Ave. SW., Washington, DC 20201.

§ 417.107 [Amended]

3. In § 417.107, the following changes are made:

a. In paragraph (i), "42 CFR part 405" is changed to "part 405 of this chapter".

b. Paragraph (j)(2)(i) is revised to read:

(j) * * *

(2) * * *

(i) A copy of the report, if any, filed with HCFA, containing the information that disclosing entities are required to report under §§ 420.206 and 455.104 of this chapter; and

§ 417.112 [Amended]

4. In § 417.112, in the concluding text at the end of paragraph (d), the superscript "1" and the corresponding footnote are removed.

§ 417.144 [Amended]

5. In § 417.144, paragraph (e) is revised to read as follows:

(e) The Secretary will publish on a monthly basis in the **Federal Register** the names, addresses, and descriptions of the service areas of the newly qualified HMOs. A cumulative list of qualified HMOs may be contained by writing the Document Control Unit, Office of Prepaid Health Care, Office of Compliance, HHS Cohen Bldg., room 4360, 330 Independence Ave., SW., Washington, DC 20201, or by visiting that Office between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday. Interested persons may contact that Office during those hours to make an appointment to obtain additional information regarding qualified HMOs.

§ 417.242 [Amended]

6. In § 417.242, paragraph (b)(7) is removed and reserved and the footnote is also removed.

§ 417.243 [Amended]

7. In § 417.243, paragraph (b), "§§ 405.480, 413.55, and 413.24" is changed to "§§ 405.480, 413.24, and 413.53".

§ 417.404 [Amended]

8. In § 417.404, paragraph (b)(1), the last sentence is removed.

§ 417.406 [Amended]

9. In § 417.406, the following changes are made:

a. In paragraph (a)(2), "§ 110.604 of this title." is changed to "§ 417.143.".

b. In paragraph (a)(2)(i), "(f)" is removed.

c. In paragraph (a)(2)(ii), the last three words "or an HMO" are removed.

d. In paragraph (a)(3), "§ 110.605 (a) through (d) of this title" is changed to "§ 417.144 (a) through (d)", and "subpart A of part 110, and § 110.603" is changed to "§§ 417.100 through 417.109, and § 417.142".

§ 417.407 [Amended]

10. In § 417.407, the following changes are made:

a. In paragraph (b), "subpart A of part 110 of this title." is changed to "§§ 417.100 through 417.109.".

b. In paragraph (c)(4), "§ 110.108(b) of this title" is changed to "§ 417.107(b)".

c. In paragraph (c)(5), "110.108(a)(1) (i) through (iv) and (a)(3) of this title." is changed to "§ 417.107(a)(1) (i) through (iv) and (a)(3)."

§ 417.408 [Amended]

11. In § 417.408, paragraph (a) the designation of (a)(1) and paragraph (a)(2) are removed and the text is run together.

§ 417.418 [Amended]

12. In § 417.418, paragraph (b), "§ 110.108(h) of this title." is changed to "§ 417.107(h).".

§ 417.478 [Amended]

13. In § 417.478, paragraph (d), "§ 110.108(j)(1) of this title" is changed to "§ 417.107".

§ 417.522 [Amended]

14. In § 417.522, paragraph (a)(3)(iii) is revised to read:

(a) * * *

(3) * * *

(iii) The successor organization meets the requirements to qualify as an eligible organization under this subpart.

§ 417.594 [Amended]

15. In § 417.594, paragraph (b)(1)(i), "§ 110.105(b) of this title;" is changed to "§ 417.104(b);".

§ 424.1 [Amended]

16. In § 424.1, the following changes are made:

a. The heading "(c) *Other applicable rules"* is inserted immediately before the concluding text of paragraph (b) that begins "Except for * * *".

b. The following sentence is added at the end of the newly designated paragraph (c):

(c) * * *

The rules for physician certification of terminal illness, required in connection with hospice care, are set forth in § 418.22 of this chapter.

Subpart B—Physician Certification Requirements

17. The heading of subpart B is revised to read as set forth above.

§ 424.10 [Amended]

18. In § 424.10, the following changes are made:

a. In paragraph (a), first sentence, "has a major role" is changed to "is the key figure".

b. In paragraph (a), "1814(a)(2)" is changed to "1814(a) (2) and (3)".

c. Paragraph (b) is revised to read as follows:

(b) *Scope.* This subpart sets forth the timing, content, and signature requirements for physician certification and recertification with respect to certain Medicare services furnished by providers.

19. In § 424.24, the following changes are made:

§ 424.24 Requirements for medical and other health services furnished by providers under Medicare Part B.

a. The section heading is revised to read as set forth above.

b. Paragraph (a)(3) is removed.

c. Paragraph (b) is revised to read as follows:

(b) *General rule.* Medicare Part B pays for medical and other health services furnished by providers (and not exempted under paragraph (a) of this section) only if a physician certifies the content specified in paragraph (c)(1), (c)(4) or (e)(1) of this section, as appropriate.

d. Paragraph (d) is removed and reserved.

§ 424.25 [Redesignated as § 410.63]

20. Section 424.25 is redesignated as § 410.63.

§ 435.725 [Amended]

21. In § 435.725, the following changes are made:

a. In paragraph (c)(2), the following heading is inserted at the beginning of the paragraph: "*Maintenance needs of spouse.*".

b. In paragraph (c)(3), the following heading is inserted at the beginning of the paragraph: "*Maintenance needs of family.*".

§ 435.733 [Amended]

22. In § 435.733, the following changes are made:

a. In paragraph (c)(2), the following heading is inserted at the beginning of the paragraph: "*Maintenance needs of spouse.*"

b. In paragraph (c)(3), the following heading is inserted at the beginning of the paragraph: "*Maintenance needs of family.*"

§ 435.832 [Amended]

23. In § 435.832, the following changes are made:

a. In paragraph (c)(2), the following heading is inserted at the beginning of the paragraph: "*Maintenance needs of spouse.*"

b. In paragraph (c)(3), the following heading is inserted at the beginning of the paragraph: "*Maintenance needs of family.*"

§ 435.1009 [Amended]

24. In § 435.1009, in the first sentence of the definition of *Institution for mental disease*, "an institution" is changed to "a hospital, nursing facility, or other institution of more than 16 beds".

§ 436.832 [Amended]

25. In § 436.832, the following changes are made:

a. In paragraph (c)(2), the following heading is inserted at the beginning of the paragraph: "*Maintenance needs of spouse.*".

b. In paragraph (c)(3), the following heading is inserted at the beginning of the paragraph: "*Maintenance needs of family.*"

§ 440.110 [Amended]

26. In paragraphs (a)(2)(i) and (b)(2)(ii), the phrase "Council on Medical Education" is changed to "Committee on Allied Health Education and Accreditation".

§ 440.140 [Amended]

27. In § 440.140(a)(2), "an institution" is changed to "a hospital, nursing facility, or other institution of more than 16 beds".

§ 447.256 [Amended]

28. In § 447.256, the following changes are made:

a. In paragraph (a), "45 CFR 201.2 and 201.3" is changed to "subpart B of part 430 of this chapter".

b. In paragraph (c), "45 CFR 201.3(g)" is changed to "subpart B of part 430 of this chapter".

§ 455.20 [Amended]

29. In § 455.20(b), "433.113 (e) and (f)" is changed to "§ 433.116 (e) and (f)".

§ 489.66 [Amended]

30. In § 489.66, in paragraph (a), the words "inpatient tuberculosis hospital services and" are removed, and "extended care services" is changed to "SNF care".

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

31. The authority citation for part 491 continues to read as follows:

Authority: Sec. 1101 of the Social Security Act (42 U.S.C. 1302).

§ 491.2 [Amended]

32. In § 491.2, paragraph (d)(3), the phrase "has been assisting" is changed to "assisted", and "immediately preceding the effective date of this subpart" is changed to "that ended on December 31, 1986".

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM

33. The authority citation for part 498 continues to read as follows:

Authority: Secs. 205(a), 1102, 1869(c) 1871, and 1872 of the Social Security Act (42 U.S.C. 405(a), 1302, 1395 ff(c), 1395hh and 1395ii), unless otherwise noted).

§ 498.3 [Amended]

34. In § 498.3, the following changes are made:

a. In paragraph (b)(10), "§ 409.10 or § 409.64" is changed to "§ 409.19 or § 410.64".

b. Paragraph (d)(2) is revised to read as follows:

(d) * * *

(2) The finding that a prospective provider does not meet the conditions of participation set forth elsewhere in this chapter, if the prospective provider is, nevertheless, approved for participation in Medicare on the basis of special access certification, as provided in subpart B of part 488 of this chapter.

c. Paragraph (d)(3) is revised to read as follows:

(d) * * *

(3) The refusal to enter into a provider agreement because the prospective provider is unable to give satisfactory assurance of compliance with the requirements of title XVIII of the Act.

(Catalog of Federal Domestic Assistance Program No. 13.714, Medical Assistance; Program No. 13.773, Medicare—Hospital Insurance; Program No. 13.774, Medicare—Supplementary Medical Insurance)

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Gail R. Wilensky,

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Louis W. Sullivan,

Secretary.

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